

**THE RISK OF ADVERSE MATERNAL AND PERINATAL OUTCOMES FOLLOWING  
AGGRESSIVE VERSUS CONSERVATIVE MANAGEMENT OF EARLY ONSET PRE-  
ECLAMPSIA WITH SEVERE FEATURES AT KENYATTA NATIONAL HOSPITAL**

**(A 6-year Retrospective Cohort Study)**

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Award of the Degree of Master of Medicine in Obstetrics and Gynaeco**

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## DECLARATION

**This research was undertaken in partial fulfillment of the degree of Master of Medicine in Obstetrics and Gynecology and was my original work and has not been undertaken and presented for a degree in any other University.**

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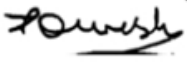
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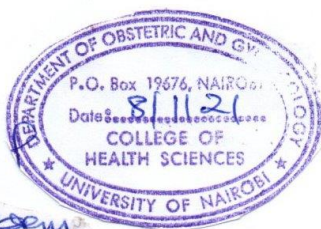
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## **DEDICATION**

To Allah the Almighty, my source of strength, guidance and hope at all times.

To my dear parents, Mr. Dida Golicha and Mrs. Hadija Hukka, for their unconditional love and support, for giving me the best education and playing a huge role in making me who I am today.

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This research is dedicated to you.

## **LIST OF ABBREVIATIONS& ACRONYMS**

ACOG – American College of Obstetricians and Gynecologists

AKI – Acute kidney injury

DBP – Diastolic blood pressure

FGR – Fetal growth restriction

HELLP – Hemolysis elevated liver enzyme and low platelets

KNH- Kenyatta National Hospital

LBW – Low birth weight

PES – Pre-eclampsia with severe features

RANZCOG - Royal Australian and New Zealand College of Obstetricians and Gynecologists

RCOG – Royal College of Obstetricians and Gynecologists

RCT- Randomized Controlled Trial

SBP – Systolic blood pressure

WHO - World Health Organization

Acronyms -C/M: Conservative Management, A/M: Aggressive Management

## LIST OF TABLES

Table 1: Study Variables.....	30
10.1: Table 2: The baseline socio-demographic characteristics of women who had aggressive management compared with those who had conservative management of early-onset PES at KNH, 2014-2019.....	35
10.2: TABLE 3: The baseline clinical characteristics of women who had aggressive compared to those who had conservative management of early-onset PES at KNH, 2014-2019.....	36
10.3: Table 4: Objective 1 – the Univariate analysis of the factors associated with adverse perinatal outcomes in women who underwent aggressive versus conservative management of early-onset PES at K.N.H, 2014-2019 .....	37
10.4 : Table 5: Objective 1 –Univariate analysis of the clinical factors associated with adverse perinatal outcomes of women on aggressive versus conservative management of early-onset PES at K.N.H, (2014-2019).....	38
10.5: Table 6: Objective 2 – Univariate analysis of the factors associated with adverse maternal outcomes among women on aggressive versus conservative management of early-onset PES at K.N.H, (2014-2019).....	39
10.6: Table 7: Objective 3: Mean ( $\pm$ SD) prolongation of Pregnancy (days) in women who underwent aggressive versus conservative management of early-onset PES at K.N.H (2014-2019).....	40
10.7: Table 8: Multivariate analysis of the factors associated with adverse perinatal outcome in women who underwent aggressive versus conservative management of early-onset PES at K.N.H, 2014-2019.....	41
10.8: Table 9: Multivariate analysis of the factors associated with adverse maternal outcomes in women who underwent aggressive versus conservative management of early-onset PES at K.N.H, 2014-2019.....	42

## LIST OF FIGURES

Figure 1: Conceptual Framework .....	26
Figure 2: Study Flowchart .....	34
Figure 3: Study Timeline .....	46



## TABLE OF CONTENTS

DECLARATION .....	2
CERTIFICATE OF AUTHENTICITY .....	<b>Error! Bookmark not defined.</b>
ACKNOWLEDGEMENTS .....	4
DEDICATION .....	5
LIST OF ABBREVIATIONS & ACRONYMS .....	6
LIST OF TABLES .....	7
<b>LIST OF FIGURES .....</b>	<b>8</b>
TABLE OF CONTENTS .....	9
ABSTRACT .....	13
1.0: OPERATIONAL DEFINITIONS .....	16
1.1: Pre-eclampsia with Severe features (PES) .....	16
1.2: Expectant/ Conservative management: .....	16
1.3: Adverse Maternal outcomes: .....	17
1.4: Adverse perinatal outcomes .....	17
2.0 INTRODUCTION .....	18
2.1 Background of the Study .....	18
3.0 LITERATURE REVIEW .....	19

3.1 Introduction.....	19
3.2 Adverse Perinatal Outcome in early-onset preeclampsia with severe features. ....	20
<b>3.2.1 Non- Reassuring Fetal Status (NRFS).....</b>	<b>20</b>
<b>3.2.2 Fetal Growth Restrictions (IUGR) and Small for Gestational Age (SGA).....</b>	<b>20</b>
<b>3.2.3 NBU admissions .....</b>	<b>20</b>
<b>3.2.4 Perinatal Mortality .....</b>	<b>21</b>
3.3 Maternal Adverse Outcomes/Complications .....	21
<b>3.3.1 Hemolysis Elevated Liver Enzymes and Low Platelets (HELLP) Syndrome .....</b>	<b>21</b>
<b>3.3.2 Pulmonary Edema .....</b>	<b>21</b>
<b>3.3.3 Renal Failure .....</b>	<b>22</b>
<b>3.3.4 Eclampsia.....</b>	<b>22</b>
3.4 Mean Prolongation of Pregnancy .....	22
3.5 Recommendations from Recognized International Bodies.....	23
<b>3.5.1. World Health Organization Support (WHO) Recommendations .....</b>	<b>23</b>
<b>3.5.2 The Royal College of Obstetricians and Gynecologists (RCOG)     Recommendations .....</b>	<b>23</b>
<b>3.5.3 The American College of Obstetricians and Gynecologists (ACOG)     Recommendations .....</b>	<b>24</b>
<b>3.5.4 The Royal Australian and New Zealand College of Obstetricians and     Gynaecologists (RANZCOG) Recommendations .....</b>	<b>24</b>

4.0 Justification .....	24
5.0 CONCEPTUAL FRAMEWORK .....	25
6.0: RESEARCH QUESTION.....	26
7.0: NULL HYPOTHESES .....	26
8.0: RESEARCH OBJECTIVES .....	26
8.1: Broad Objective .....	26
8.2 Specific Objectives: .....	26
<b>8.2.1 Primary .....</b>	<b>26</b>
<b>8.2.2 Secondary.....</b>	<b>27</b>
9.0: METHODOLOGY .....	28
9.1: Research Design .....	28
9.2: Research Setting .....	28
9.3: Sample Size Determination .....	29
9.4: Sampling Technique and Recruitment.....	29
9.5: Inclusion and Exclusion Criteria .....	30
9.6: Study Variables.....	30
9.7: Study Procedures .....	31
<b>9.7.1: Ethical Procedures.....</b>	<b>31</b>
<b>9.7.2: Training of Research Team .....</b>	<b>31</b>

<b>9.7.3: Data Collection Procedures</b> .....	<b>32</b>
<b>9.7.4: Data Quality Assurance</b> .....	<b>32</b>
9.8: Data Management and Analysis .....	32
<b>9.8.1 Data Management</b> .....	<b>32</b>
9.8.2: Data Analysis and Presentation .....	33
10.0 RESULTS .....	34
11.0: Discussion.....	43
12.0: Conclusion: .....	44
13.0: Recommendations:.....	44
14.0: Study Limitations & Strengths: .....	45
14.1: Limitations.....	45
14.2: Strengths .....	45
15.0 Study Timelines .....	46
16.0 REFERENCES .....	47
17.0 APPENDICES .....	50
17.1: APPROVAL FROM KNH-UON ERC .....	50
17.2: APPENDIX 2: STUDY TOOL .....	51

## **ABSTRACT**

### ***BACKGROUND:***

Preeclampsia refers to onset of hypertension after 20 weeks of gestation in a previously normotensive patient in presence proteinuria, platelet count <100,000/microL, elevated serum creatinine, at least twice liver transaminases, pulmonary edema, new-onset and persistent headache not accounted for by alternative diagnoses and not responding to usual doses of analgesics, and visual symptoms such as blurred vision, flashing lights or sparks, or scotomata.

Preeclampsia complicates 5-8% of pregnancy. In addition, it is among the leading causes of morbidity and mortality to both the mother and the perinate. The management of preeclampsia without severe features has ordinarily been based on the count of balancing the interests of the mother with those of the fetus. Conversely, Preeclampsia with Severe Features (PES) has been managed by expedited fetus delivery the gestation age notwithstanding. In the contemporary era, the availability of improved approaches for monitoring both maternal and fetal progress has increased criticisms for the traditional approach of expedited delivery (aggressive management). The bottom line argument is that mothers who are stable but with early-onset PES (24-34 weeks) can have their delivery delayed cautiously (conservative management) with the aim of improving perinatal outcomes without compromising maternal safety.

In previous studies in USA, the average latency period was 15.4 days without eclampsia or perinatal death following expectant management. Also, expectant management had decreased the incidence of admission to the new born unit and neonatal complications. Although a few regional studies have been conducted in South Africa, Odendaal et al and Hall et al suggest similar outcomes. There are no studies to inform local guidelines, protocols and practice. In this retrospective cohort study, we sought to estimate the mean duration of latency for conservative management, and to compare the perinatal and maternal outcomes of conservative compared to aggressive management of early-onset PES at KNH so as to inform development of guidelines, protocols and practice.

### ***OBJECTIVE:***

To compare the risk of adverse maternal and perinatal outcomes of women undergoing aggressive versus conservative management of early-onset PES at Kenyatta National Hospital between January 2014 and December 2019

### ***METHODS:***

The study was a retrospective cohort study with data collected from medical records of pregnant women with PES at 24 – 34 weeks gestation from 1st January 2014 to 31st December 2019. A total of 452 pregnant women with PES at 24 – 34 weeks gestation of whom, 226 underwent conservative management and 226 underwent aggressive management were sampled consecutively and followed until delivery to assess for perinatal and maternal outcomes. Conservative management was defined as prolonging pregnancy to improve perinatal outcomes in pregnant women with early-onset PES who have completed the dose of antenatal corticosteroids and 24 hours post-admission and are in stable condition. Aggressive management was defined as administration of antenatal corticosteroids followed by immediate delivery of pregnant women with early-onset PES so as to reduce the risk of adverse maternal outcomes. Baseline socio-demographics were compared using t-test for continuous data and frequency and proportions for categorical variables. Simple logistic regression was used to compare association between type of management (aggressive or conservative) and outcome (perinatal or maternal outcome) and crude odds ratio with 95% confidence interval were used for its presentation. Multiple logistic regression analysis was carried out to determine the factors affecting the association between outcome and exposure. P value of 0.05 was considered statistically significant. The data was analyzed using STATA 15 and presented in form of charts, tables, and as narrative.

### ***RESULTS:***

Between January 2014 and December 2019, a total of 3,619 medical records of pregnant women with PES at 24 – 34 weeks gestation, admitted between January 2014 and December 2019 were extracted and reviewed. Of these, 640 records were assessed for eligibility of which, 452 met the eligibility criteria. 226 were in the conservative and 226 were in the aggressive arm of

management. 188 were excluded due to missing data. The mean (sd) prolongation of pregnancy was 16.4(16.6). On multi-variate analysis, babies born to women who underwent aggressive management had a 1.4 times greater odds of developing adverse perinatal outcomes than those born to women on conservative management with an OR of 1.41, 95% C/I of (0.95-2.15) which was not statistically significant. In multi-variate analysis, women on aggressive management had a 2.4 times higher odds of developing adverse maternal outcomes than those on conservative management with an OR of 2.39, 95% C/I of (1.24-4.60) which was statistically significant.

### ***CONCLUSION:***

This study has showed that aggressive management was associated with 2.4 times higher risk of developing adverse maternal outcomes compared with conservative management of early-onset PES. The risk of adverse perinatal outcomes was found to be non-statistically significantly greater in the A/M arm compared to the C/M arm of early-onset PES. In addition, conservative management of early-onset PES had a mean(standard deviation) prolongation of pregnancy of 16.4(16.6) days.

### ***RECOMMENDATIONS:***

Pregnant women with early-onset PES eligible for conservative management should be offered under close monitoring and advised that it takes on average two weeks from admission to delivery with a decreased odds of risk of maternal adverse outcomes. The study results will be instrumental in informing policy and local guidelines on management of early-onset pre-eclampsia with severe features. In addition, a larger prospective study with a prolonged follow-up period of newborns should be conducted in the future to provide better insight on the outcomes.

## **1.0: OPERATIONAL DEFINITIONS**

### **1.1: Pre-eclampsia with Severe features (PES)**

Is defined as new-onset hypertension after 20 weeks of pregnancy with a systolic blood pressure of 160 mm Hg or more, or diastolic blood pressure of 110 mm Hg or more on two occasions at least 4 hours apart with or without proteinuria. OR

Systolic blood pressure of 140 mm Hg or more or diastolic blood pressure of 90mm Hg or more on two occasions at least 4 hours apart with or without proteinuria with at least one of the following features of target organ dysfunction.

- Thrombocytopenia (platelet count less than  $100,000 \times 10^9/L$ )
- Impaired liver function as indicated by abnormally elevated blood concentrations of liver enzymes (transaminases twice the upper limit normal concentration), and severe persistent right upper quadrant or epigastric pain unresponsive to medication and not accounted for by alternative diagnoses
- Renal insufficiency (serum creatinine concentration more than 1.1 mg/dL or a doubling of the serum creatinine concentration in the absence of other renal disease)
- Pulmonary edema
- New-onset severe headache unresponsive to medication and not accounted for by any other illness.

### **1.2: Expectant/ Conservative management:**

Is defined as the delayed delivery approach for management of early-onset PES aimed at buying time for fetal maturity that should be 24-48 hours from the time of admission in a patient who has completed antenatal corticosteroids.

#### **Indications:**

PES based on transient laboratory abnormalities alone –



Asymptomatic women [ALT, AST] twice the upper limit of normal, platelet counts less than 100,000 cells/microL). The laboratory tests (AST, ALT, platelet count) should be repeated every 6 to 12 hours to monitor improvement.

PES based on high blood pressure criteria alone:

Antihypertensive agents are given to control severe hypertension and allowed to undergo expectant management.

### **1.3: Adverse Maternal outcomes:**

Are defined as the life threatening maternal complications related to PES during the perinatal period mainly eclampsia, stroke, pulmonary edema, HELLP syndrome, myocardial infarction, and new or worsening renal dysfunction.

### **1.4: Adverse perinatal outcomes**

These are life-threatening complications related to PES during perinatal period. The lists of such conditions include non-reassuring fetal status (NRFS), fetal growth restriction, respiratory distress syndrome, newborn unit admission, and perinatal mortality.

## 2.0 INTRODUCTION

### 2.1 Background of the Study

Preeclampsia with severe features (PES) is defined as new-onset hypertension after 20 weeks of pregnancy with a systolic blood pressure of 160 mm Hg or more, or diastolic blood pressure of 110 mm Hg or more on two occasions at least 4 hours apart with or without proteinuria. Preeclampsia is also described characterized by a systolic blood pressure of 140 mm Hg or more, or diastolic blood pressure of 90mm Hg or more on two occasions at least 4 hours apart with or without proteinuria with at least one of the following features of target organ dysfunction. The Incidence of PES, in study published in 2016 in Thailand was 9.5 per 1,000 deliveries.(1)

Early-onset PES presents a dilemma to the Obstetrician with some choosing the expectant management route in a bid to attain fetal maturity and reduce neonatal morbidity & mortality. However, traditionally, the general consensus has been to deliver mothers with PES after stabilization regardless of gestation to prevent maternal adverse outcomes .(2)

Ordinarily, once PES is diagnosed, the traditional course of action is to deliver the baby since the condition is progressive with unsatisfactory medical treatment. However, in the recent days, the long held practice of hastened delivery is being questioned. Recommendations are put forth from previous studies to prolong the pregnancy in most cases of severely premature pre-eclamptic gestations. The prolonging of pregnancy, which is a cautious practice to consider delivery after there is fetal lung maturity or fetal or maternal distress, or attaining a gestational age of 34 to 36 weeks. (3)

The clinical course of early onset PES justifying expedited delivery is premised on the fact PES accelerates maternal deterioration until the fetus is expelled. Therefore, since fetal expulsion is the only guaranteed approach for preventing further complications, scholars and experts hold that the fetus should be delivered in case the maternal develops multi-organ dysfunction, fetal distress or reaching fetal gestation of 34 weeks. (4)

Despite the call for expedited delivery, available evidence indicates that fetal expulsion at lower gestations i.e. less 24 weeks, is linked to increased risks of perinatal mortality and morbidity secondary to severe prematurity. Furthermore, evidence shows that in pre-eclamptic pregnancies, the fetal lung maturity is significantly compromised. At that early gestation, prolonging the pregnancy also increases the risks of maternal complications including mortality, especially due to the longevity of care for the mother. Consequently, the proponents of aggressive care developed guiding management policies.

The bottom line principle for managing early onset PES is maximizing survival rate for the mother, or the mother and the fetus through a calculated balance of the potential benefits against the potential dangers. The notable danger to mothers with PES include death or cerebral haemorrhage. The findings reported by two recent randomised controlled trials revealed promising perinatal outcomes in conservative management approach.<sup>(5)</sup> However, the maternal safety in conservative management must be evaluated over longer periods as the serious maternal complications are less frequent. It is important to note that despite the fact that the approach can be effective in controlling serious maternal complications, the fetus should be delivered as the earliest gestation considered to be sufficient mature for elective delivery.

This study will determine the risk of adverse maternal and perinatal outcomes of early-onset PES in aggressive versus conservative management at KNH.

### **3.0 LITERATURE REVIEW**

#### **3.1 Introduction**

The chapter collates evidence from past studies relevant and significant to the understanding of the current study. The review of empirical evidence is organized thematically guided by the main study objectives. In an overview, this chapter focuses on the evidence on adverse perinatal outcomes, adverse maternal outcomes, mean latency of pregnancy and international guidelines on management of early-onset PES.

## **3.2 Adverse Perinatal Outcome in early-onset preeclampsia with severe features.**

### **3.2.1 Non- Reassuring Fetal Status (NRFS)**

In a multi-center R.C.T in Latin America, the MEXPRES LATIN study, on comparison of maternal and perinatal outcomes in conservative versus and aggressive management of early-onset PES, showed NRFS was lower in CM was 46.0% versus 52.4% in A/M (6). In another study by Sarsam et al, on expectant versus aggressive management in preeclampsia with severe features remote from term, showed NRFS was lower in C/M group at 22.86% versus 58.97% in A/M group.(7)

In the U.S.A, in a study by Sibai et al, on the evaluation and management of severe preeclampsia before 34 weeks of gestation, the C/M group had a lower incidence of RDS of 22.4 % versus 50% in the A/M group. (8)

### **3.2.2 Fetal Growth Restrictions (IUGR) and Small for Gestational Age (SGA)**

FGR and SGA are common adverse perinatal outcome among mothers with early-onset PES. In an RCT by Sibai et al in 1994 to assess maternal and neonatal outcome for expectant management of early-onset PES, Small for gestation was at 30.1%. (9) In another study by Sarsam et al on the outcomes of expectant versus aggressive management in PES remote from term, incidence of IUGR was lower in the C/M arm at 15.38% versus 31.42% in A/M arm. (7) In Netherlands, Wallenburg et al studied the maternal and perinatal outcomes of expectant management of PES remote from term and found the incidence of SGA to be 58.1% .(2)

### **3.2.3 NBU admissions**

In an RCT by Sibai et al to assess maternal and neonatal outcomes for both expectant and aggressive management of early-onset PES, the NBU admissions was found to be lower in C/M arm i.e 76% versus 100% in the A/M.(9) In a multicenter RCT, the MEXPRES latin study, NBU admissions were noted to be lower in the C/M arm at 69.3% in C/M versus 73.9% in A/M arm. (6). Locally, in a retrospective study by E. Warren C et al, to assess the clinical presentation and

outcomes of preeclampsia and eclampsia at a national hospital in Kenya; NBU admissions were noted to be higher in the early-onset PES at 55% versus 24.3% in the late-onset PES. (10)

### **3.2.4 Perinatal Mortality**

In a study done in Iraq by Sarsam et al, the incidence of perinatal mortality was lower in the C/M arm i.e 11.43% versus 25.64% in A/M arm. the MEXPRES Latin study conducted in Latin America, perinatal mortality was lower in the C/M arm i.e 8.7% versus 9.4% for A/M arm.(6) Sibai et al conducted a study to assess the maternal and neonatal outcomes for both expectant and aggressive management of early-onset PES, the perinatal mortality in the study was 0 % for both groups. (8). In Egypt, Abdel Hady et al conducted a prospective observational study on maternal and prenatal outcomes of expectant management of PES remote from term, which showed a perinatal mortality of 48.3%. (11) In Kenya, in a retrospective study by E. Warren et al, the still births were noted to be higher in the early-onset PES at 33.9% versus 9.4% in late-onset PES group.(10)

## **3.3 Maternal Adverse Outcomes/Complications**

### **3.3.1 Hemolysis Elevated Liver Enzymes and Low Platelets (HELLP) Syndrome**

In the MEXPRES Latin Study, the incidence of HELLP was noted to be 13.5% in C/M arm versus 16% in A/M arm (2). In a Prospective case series by Hall et al in South Africa, to evaluate maternal outcomes of expectant management of early-onset PES, the incidence of HELLP was at 5.2%.(12). Also in South Africa, Oettle et al conducted a prospective case series to determine the safety of expectant management of PES at secondary level hospital, in which HELLP was noted to be at 4.6%.(12) In Kenya, in a retrospective study by E. Warren et al, HELLP syndrome was noted to be higher in the early-onset PES at 13% versus 3% in the late-onset group.(10)

### **3.3.2 Pulmonary Edema**

In a study by Sarsam et al, on Expectant versus aggressive management of PES remote from term, pulmonary edema was noted to be at 2.86% in C/M versus 7.69% in A/M. In another study

by Hall et al, 2000 in South Africa, to evaluate the maternal outcomes of expectant management of early-onset PES, the incidence of pulmonary Edema was at 2.1 %. (12) Oettle et al. in 2005 conducted a study to determine the safety of expectant management of PES at secondary level hospital, in South Africa where he found the incidence of pulmonary edema was at 0.8%. (4)

### **3.3.3 Renal Failure**

In Prospective Cohort Study carried out by Sarsam et al, on expectant versus aggressive management of preeclampsia with severe features remote from term, renal impairment was noted in 2.86% of C/M arm versus 2.56 % of the A/M arm. An observational study conducted in 1993 by Olah et al in the United Kingdom reported 3.6% prevalence of renal complications among 28 mothers with early-onset PES during expectant management approach.(13) In Kenya, in a retrospective study by E. Warren et al, renal failure was noted to be higher in the early-onset PES at 5.8% versus 3.5% in the late-onset group(10)

### **3.3.4 Eclampsia**

In a study by Oettle et al, 2.3% cases of eclampsia were noted following conservative management of mothers with early-onset PES(12). In another Prospective cohort study by Sarsam et al, on expectant versus aggressive management of PES remote from term, eclampsia was found in 2.86% of the C/M arm versus 17.95% of A/M arm. In the MEXPRE latin study, on the maternal and neonatal outcomes of expectant versus aggressive management of early-onset PES, eclampsia was found in 0.75% of those in C/M arm, versus 0.76% of those in the A/M arm.(6)

### **3.4 Mean Prolongation of Pregnancy**

Sarsam et al. carried out a study on expectant versus aggressive management of preeclampsia with severe features remote from term. They found a mean (sd) prolongation of pregnancy of 9.2 days (3-8). In an RCT conducted by Sibai et al to determine the maternal and neonatal

outcomes of expectant versus aggressive management of early-onset PES, the mean(sd) prolongation of pregnancy was 15.4 (4-36) (8). In an RCT conducted by Odendaal et al, in South Africa to compare the maternal and perinatal outcomes following conservative versus aggressive management of early-onset PES, the mean prolongation of pregnancy was 7.1 days.(14)In Kenya, in a retrospective study by Warren et al, prolonged hospital stay i.e. > 1 week was noted to be higher in the early-onset PES at 67% versus 24% in the late-onset group.

### **3.5 Recommendations from Recognized International Bodies**

#### **3.5.1. World Health Organization Support(WHO) Recommendations**

The WHO supports the delayed delivery approach for patients with early-onset PES who have a viable fetus.(15) However, the expectant management should be implemented only when the maternal hypertension is controlled, with a stable fetus and in the absence of target organ dysfunction. The expectant management is expected to buy more time for the fetal maturity, thereby improving fetal survival rates.(9)

#### **3.5.2 The Royal College of Obstetricians and Gynecologists (RCOG) Recommendations**

RCOG concurs with WHO recommendations on prolonging the pregnancy in cases where the gestation is below 34 weeks.(16) However, this should only occur in cases where the mother remains stable and the fetus is viable. The target is to delay the delivery by at least 24 hours, and during that waiting period, the mother should receive antenatal corticosteroids to help in fetal lung maturity.(17)The RCOG relies on a number of randomized controlled trials which indicated lower incidence of neonatal complications on conservative management approach to manage early-onset PES where delivery was prolonged for 7 to 15 days for gestations between 24 weeks and 34 weeks.(18) In a study by Pasquier et al., the expectant management approach also proved crucial towards reducing neonatal complications for gestations as low as 24 weeks.(19)

### **3.5.3 The American College of Obstetricians and Gynecologists (ACOG)**

#### **Recommendations**

ACOG also recommends the expectant management approach for Early-onset PES.(20) The delay is aimed at ensuring a lower risk of neonatal complications. The approach should only be used in situations with low maternal risks. ACOG emphasizes on the vitality of vibrant, strict, and close monitoring of both maternal and fetal status. Corticosteroids should be administered for fetal lung maturity.(21)

### **3.5.4 The Royal Australian and New Zealand College of Obstetricians and**

#### **Gynaecologists (RANZCOG) Recommendations**

RANZCOG further cements the importance of buying time as much as possible without compromising both maternal and fetal safety.(22) In Early-onset PES, delivery could be delayed for 24-48 hours provided the maternal and fetal parameters are stable, so as to allow administration of antenatal corticosteroids. (4)In addition, this time allows magnesium sulphate to be administered antenatally to confer neonatal neuro-protection.(23) The expectant delivery should not be undertaken in instances where the maternal or fetal conditions are unstable.

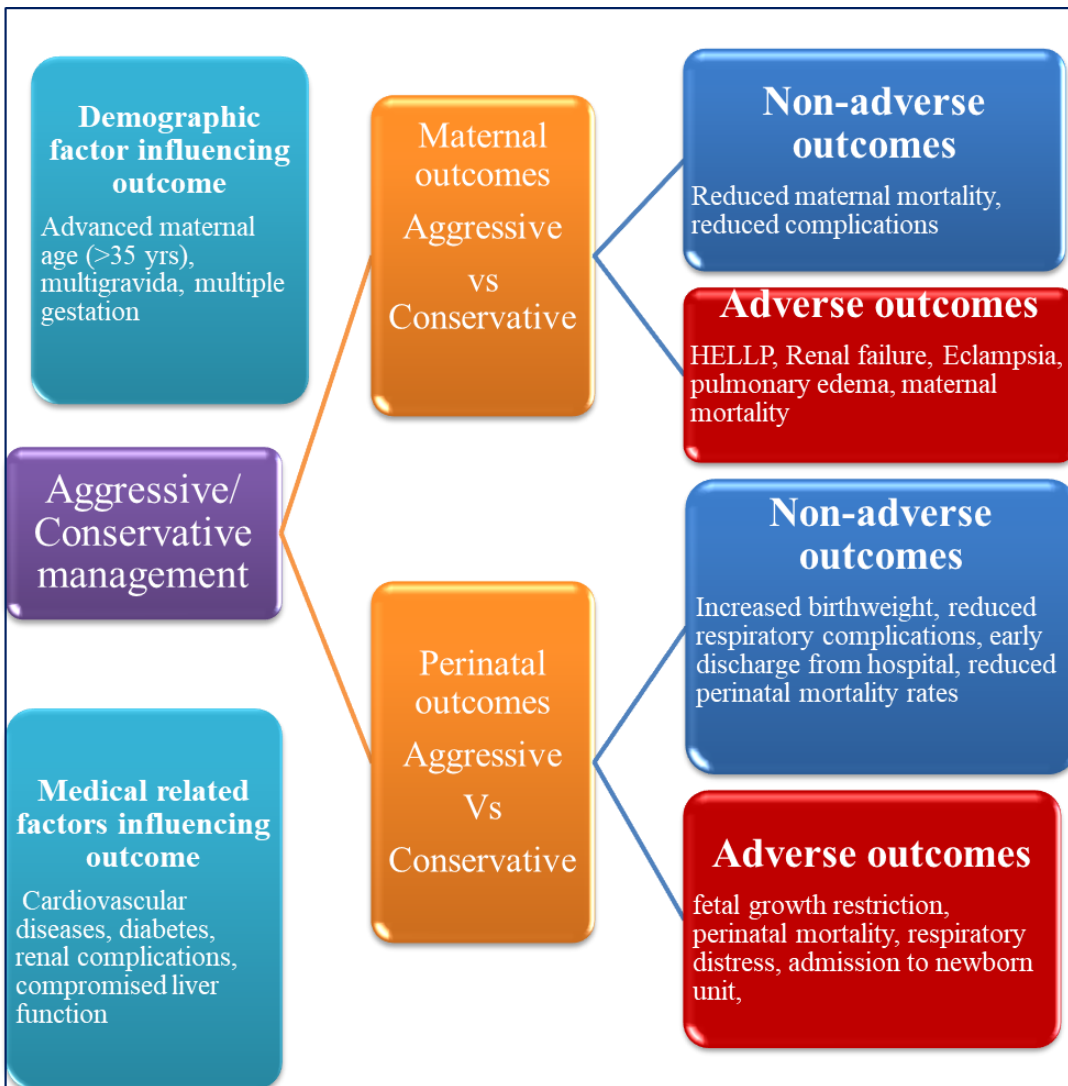
## **4.0 Justification**

Early-onset PES poses a decision making dilemma for the obstetrician. The disease being progressive with no medical treatment, delivery of the baby is always in the best interest of the mother. Conservative Management is meant to achieve fetal lung maturity before delivery at 34 weeks of gestation. Aggressive management is usually to avert maternal complications where delivery is done after stabilization of the mother but with increased risk of fetal complications. No recent studies in Sub-Saharan Africa, yet we have high burden of PES. There are no studies on outcomes or guidelines for conservative management of PES in the region or Kenya.



## 5.0 CONCEPTUAL FRAMEWORK

The conceptual framework (see the *figure 1* below) illustrates the association of the independent variable, versus the dependent variable, and the outcomes that will be of critical interest in this study.



### ***Figure I: Conceptual Framework***

In figure 1 above, the Socio-demographic factors like advanced maternal age, multigravida and medical conditions like diabetes and renal disease are associated with increased risk of adverse outcomes in management of early-onset PES. Management can either be aggressive or conservative approach and each of the two can have adverse and non-adverse maternal and perinatal outcomes. This study focused on the adverse perinatal and adverse maternal outcomes.

#### **6.0: RESEARCH QUESTION**

Are there differences in the risk of adverse maternal and perinatal outcomes of aggressive management compared to conservative management of early-onset PES (24-34 weeks) at Kenyatta National Hospital?

#### **7.0: NULL HYPOTHESES**

There are no differences in the risk of adverse maternal and perinatal outcomes of aggressive management compared to conservative management of early-onset PES (24-34 weeks) at Kenyatta National Hospital.

#### **8.0: RESEARCH OBJECTIVES**

##### **8.1: Broad Objective**

To compare the risk of adverse maternal and perinatal outcomes of aggressive versus conservative management of early-onset PES at Kenyatta National Hospital

##### **8.2 Specific Objectives:**

###### **8.2.1 Primary**

- To compare the risk of adverse perinatal outcomes of aggressive versus conservative management of early-onset PES at KNH.

- To compare the risk of adverse maternal outcomes of aggressive versus conservative management of early-onset PES at KNH.

### **8.2.2 Secondary**

- To compare the duration of time from admission to delivery following aggressive versus conservative management of early-onset PES at KNH.

## **9.0: METHODOLOGY**

### **9.1: Research Design**

The study adopted a retrospective cohort study design.

The population consisted of pregnant women with PES at 24 -34 weeks

Exposed group: Conservative management (C/M)

Unexposed group: Aggressive management (A/M)

Outcomes:

- Adverse perinatal outcomes which include Non-Reassuring Fetal Status (NRFS), Fetal Growth Restriction (FGR), Perinatal mortality, Admission to NBU, Respiratory Distress Syndrome (RDS).
- Adverse maternal outcomes that include Eclampsia, HELLP syndrome, New or worsening renal dysfunction (serum creatinine greater than 1.1 mg/dL or twice baseline), Pulmonary edema, Neurological impairment and maternal mortality.
- The mean(standard deviation) prolongation of pregnancy in days

Timeline- 6 years (Jan 2014 to Dec 2019)

Setting: KNH- Antenatal, Postnatal and Labor Wards

Sampling: consecutive sampling of patient's records.

### **9.2: Research Setting**

The research was conducted at Kenya's biggest referral hospitals, Kenyatta National Hospital, which is located in Nairobi County. Given the study population is mothers with pre-eclampsia with severe features, the main department in the hospital concerned is the maternity department. The study setting was selected for its appropriateness given that most cases with PES are referred to this institution as the national referral center. The hospital serves close to 70,000 inpatients and 500,000 outpatient clients in all departments. In Kenyatta National Hospital, roughly 12,000-15,000 deliveries are conducted in the maternity department annually, out of these an average 560 cases of PES patients are managed at the maternity inpatient department annually.

### 9.3: Sample Size Determination

The sample size was calculated using the formula for comparing two proportions, two samples with two sided equality using the sample size calculator as shown, taking  $p$  as the estimated proportion of perinatal mortality in aggressive versus conservative group of mothers with PES, which is 25.4 % versus 11.43% respectively, based on a study by Sarsam et al (2008). (7)

$$n_A = \kappa n_B \text{ and } n_B = \left( \frac{p_A(1-p_A)}{\kappa} + p_B(1-p_B) \right) \left( \frac{z_{1-\alpha/2} + z_{1-\beta}}{p_A - p_B} \right)^2$$

$$1 - \beta = \Phi(z - z_{1-\alpha/2}) + \Phi(-z - z_{1-\alpha/2}) \quad , \quad z = \frac{p_A - p_B}{\sqrt{\frac{p_A(1-p_A)}{n_A} + \frac{p_B(1-p_B)}{n_B}}}$$

where

$\kappa = n_A/n_B$  is the matching ratio  
 $\Phi$  is the standard Normal distribution function  
 $\Phi^{-1}$  is the standard Normal quantile function  
 $\alpha$  is Type I error  
 $\beta$  is Type II error, meaning  $1 - \beta$  is power

Taking a ratio for the aggressive to conservative group of 1:1, the calculated sample size was 205 participants per arm,(10% markup to make up for missing data, lost to follow-up i.e. managed in KNH but delivered elsewhere). This brought the sample size per arm to 226.

**Calculated sample size: 226 per arm, Total: 452**

### 9.4: Sampling Technique and Recruitment

The study used consecutive sampling technique. In this non-probability sampling approach, every subject who qualified for the inclusion criteria was identified for enrollment until the desired sample size was achieved.

All the files for the patients with a diagnosis of preeclampsia with severe features were identified from the health records department for review. Only files with complete data and that fit the inclusion criteria were selected for data extraction and the process was started from files of January 2019 and continued up to December 2014 until the desired sample size for each of the arms was achieved.

## **9.5: Inclusion and Exclusion Criteria**

### **9.5.1: The inclusion criteria: Pregnant women were eligible if they;**

- Had preeclampsia with severe features
- Were at gestation age of 24 – 34 weeks
- Had completed 24 hours from the time of admission
- Had completed antenatal corticosteroids dose.

### **9.5.2: Pregnant women were excluded if they had;**

- Non-viable fetus
- Medical complications e.g. Diabetes, Chronic renal failure, Chronic Hypertension
- Preterm labor
- Preterm Premature Rupture of Membranes (PPROM)
- Congenital fetal anomalies

## **9.6: Study Variables**

**Table 1: Study Variables**

Variable	
Independent	Conservative or Aggressive Management of early-onset PES
Dependent	Adverse fetal outcomes Adverse maternal outcomes Mean prolongation of Pregnancy

## **9.7: Study Procedures**

### **9.7.1: Ethical Procedures**

All researchers adhered to research ethics by observing due diligence in the whole process of research approval, and data management (collecting, storage, and analysis).(24) Although the study was purely reliant on patients' files, there was need to ensure patients' details and information was handled carefully. As prescribed and recommended in the HIPAA (Health Insurance Portability and Accountability Act), confidentiality, anonymity, and privacy was upheld by ensuring that no personal data was indicated in the data collection tools.

Ethical approval was sought and obtained from the KNH-UoN Ethics Review Committee before collection of data. Additionally, approval to access the records at the KNH HMIS was sought from the KNH research committee and the medical records department. Data collection was done by trained clinicians, who, under the guidance of the PI, upheld confidentiality. No harm was expected in this study, being that it is a retrospective study with data collection from secondary sources. The researcher took full responsibility in storing and securing collected data to avoid instances where data may fall into wrong hands that may use the data maliciously.(25)

The data collected was used only for the sole purpose of completing the study at hand. Under no circumstance did the researcher use the data for other gains or purposes.

### **9.7.2: Training of Research Team**

The study team, comprised of the principal investigator, 3 research assistants and the data manager were trained on confidentiality, data collection and were fully oriented on the use of the data collection tools.

### **9.7.3: Data Collection Procedures**

The researcher used the specially designed data abstraction tool to abstract data from the patients' files. The cases were traced from the information registry in health records department. In collaboration with three research assistants, the relevant data as per the study tool was abstracted. Each patient file was considered as a single source; thus, the data was a document in a single study tool. The collected data was then uploaded onto a password protected excel sheet managed by the data manager for data cleaning and verification.

### **9.7.4: Data Quality Assurance**

A sample of 10 data abstraction tools were pre- tested and analyzed before a final draft was used. The research assistants were trained on appropriate data abstraction techniques and filling the tools. Recordings of clinical findings were entered after thorough scrutiny of the records and second checking with the PI any time there was doubt. Unique identifiers were assigned to all the study participants. If double entries were discovered, one of the data abstraction tools was withdrawn, discarded and serialization rectified. Information filled on the questionnaires was checked for any errors and corrected on a daily basis.

## **9.8: Data Management and Analysis**

### **9.8.1 Data Management**

Once the data was collected, it was stored in a secure lockable locker, where only the researcher could access or grant access to research assistants. The data was then shared with the statistician for analysis. According to the University protocol, the collected data was stored safely in case of need to access it for up to three years for academic research, after which the data can be discarded by the researcher. The data was not used or re-used for any other purpose outside the current study.



### **9.8.2: Data Analysis and Presentation**

Data was analyzed using STATA 15.

Before analysis, the variables were checked for outliers, inconsistencies, missing data and distribution. Visual inspection of all continuous variables using scatter plots, box plots or histograms was done to identify outliers and distribution of the data. Some of the values in the categorical variables were grouped especially where the subgroups had small numbers.

Adverse maternal outcome was defined as the presence ofHELLP, eclampsia, pulmonary oedema, and maternal mortality.

Descriptive analysis was done in the form of mean (standard deviation), median (interquartile range) and frequencies (percentages) and presented in form of tables.

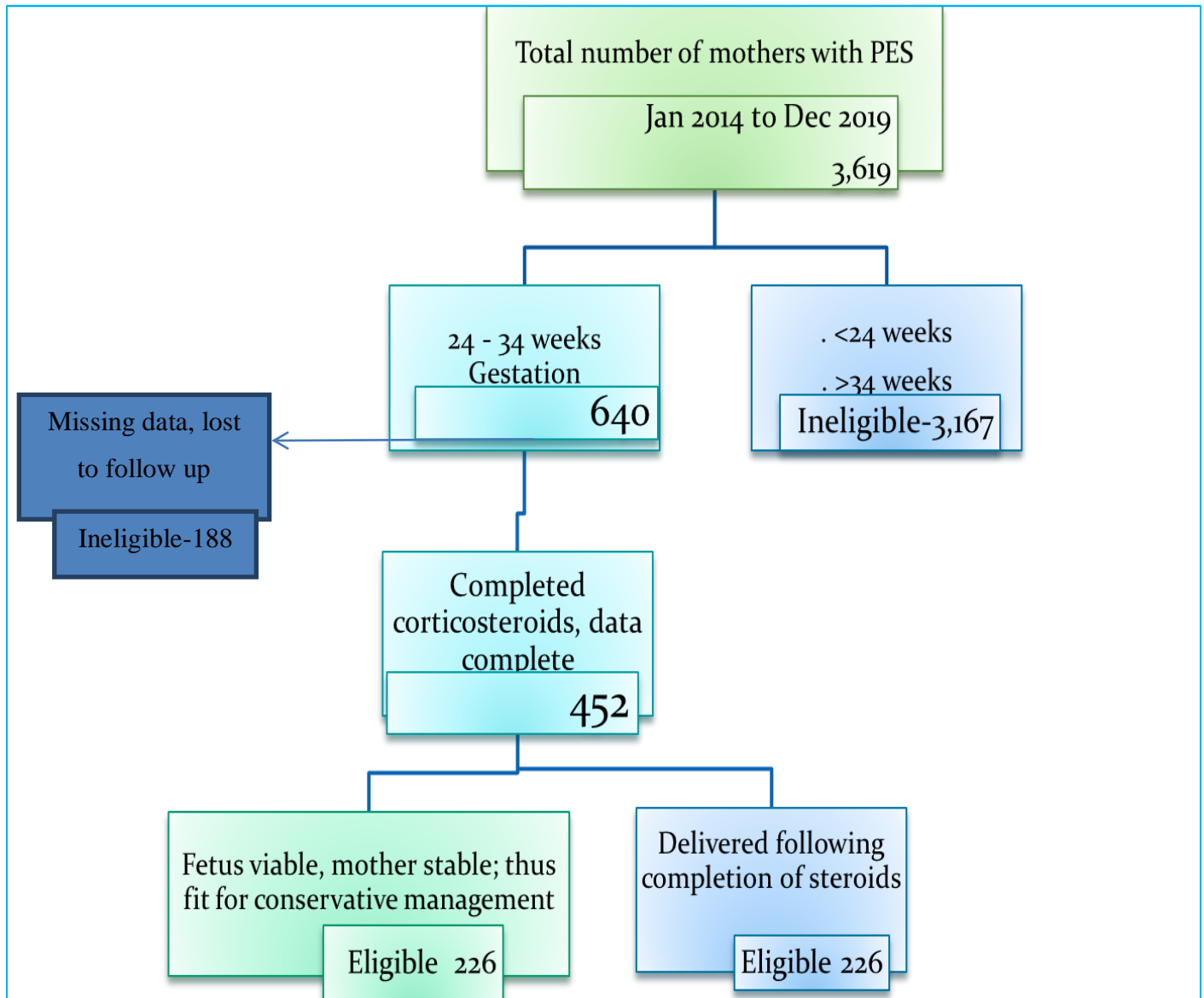
Inferential univariate analysis was carried out to determine whether the observed differences in the socio-demographic and clinical characteristics were due to chance. Chi square and student T test were used to test for statistical significance. Wilcoxon rank sum test was used for non-normally distributed continuous variables while Fishers' exact test was used where frequencies were small.

Simple logistic regression was used to compare association between type of management (aggressive or conservative) and outcome (perinatal or maternal outcome) and crude odds ratio with 95% confidence interval were used for its presentation. Each of the covariates was checked for association with exposure and outcome.

Multiple logistic regression analysis was carried out to determine the factors affecting the association between outcome and exposure.

## 10.0 RESULTS

*Figure 2: Study Flowchart*



In figure 2 above, the study flow-chart shows that between January 2014 and December 2019, a total of 3,619 medical records of all pregnant women with PES were reviewed, out of which 640 were at 24 – 34 weeks gestation. 2,979 medical records were excluded as they were < 24 weeks and > 34 weeks of gestation. Out of the 640 records that were assessed for eligibility, 452 completed steroids and had complete data. 226 were in the conservative and 226 were in the

aggressive arm of management. 188 were excluded due to missing data, or due to a patient being lost to follow up i.e. started management in KNH but delivered elsewhere so maternal and perinatal outcomes could not be assessed.

**10.1: Table 2: The baseline socio-demographic characteristics of women who had aggressive management compared with those who had conservative management of early-onset PES at KNH, 2014-2019**

Socio-demographic characteristics		Total N= 452	Aggressive N =262	Conservative n= 262	P value
Age	(mean/SD)	30.1 (5.6)	29.8 (5.7)	30.4 (5.4)	0.212
Age category	< 30 years	243 (53.8%)	127 (56.2%)	116 (51.3%)	0.30
	>30 years	209 (46.2%)	99 (43.8%)	110 (48.7%)	
Marital status	Single	68 (15.0%)	38 (16.8%)	30 (13.3%)	0.29
	Married	384 (84.9%)	188 (83.2%)	196 (86.7%)	
Education	None/Primary	118 (26.1%)	67 (29.7%)	51 (22.6%)	0.026
	Secondary	165 (36.5%)	69 (30.5%)	96 (42.5%)	
	Tertiary	169 (37.4%)	90 (39.8%)	79 (34.9%)	
Occupation	Unemployed/student	228 (50.4%)	121 (53.6%)	107 (47.3%)	0.294
	self-employed	143 (31.6%)	64 (28.3%)	79 (35.0%)	
	formal employed	81 (18.0%)	41 (18.1%)	40 (17.7%)	
Religion	Christian	448 (99.1%)	225 (99.6%)	223 (98.7%)	0.312
	Muslim	4 (0.9%)	1 (0.4%)	3 (1.3%)	

The differences in proportions between the women who underwent aggressive compared with those who underwent conservative management were statistically similar, in terms of age, marital status, occupation and religion.

Among women with primary level of education, the proportion of those who underwent aggressive management was significantly higher compared to those who had conservative management, 29.7% versus 22.6%, p-value=0.026.

Among women with secondary level of education, the proportion of those who underwent conservative management was significantly higher compared to those who had aggressive management, 42.5% versus 30.5%, p-value=0.026.

Among women with tertiary level of education, the proportion of those who underwent aggressive management was significantly higher compared to those who had conservative management, 39.8% versus 34.9%, p-value=0.026.

**10.2:TABLE 3: The baseline clinical characteristics of women who had aggressive compared to those who had conservative management of early-onset PES at KNH, 2014-2019**

Clinical characteristics		Total N= 452	Aggressive N =226	Conservative n= 226	P value
Parity	Primiparous	140 (31.0%)	62 (27.4%)	78 (34.5%)	0.266
	Previous miscarriage	63 (13.9%)	33 (14.6%)	30 (13.3%)	
	Multiparas	249 (55.1%)	131 (58.0%)	118 (52.2%)	
Gravidity	Primigravida	92 (21.6%)	47 (21.3%)	45 (19.9%)	0.723
	Multigravida	355 (79.4%)	174 (78.7%)	181 (80.1%)	
Gestation in weeks	Mean (SD)	30 .3 (4.7)	30.3 (4.6)	30.3 (4.7)	0.977

In table 3 above, in terms of parity, gravidity & gestation (in weeks) , the proportions of women who had aggressive compared to those who had conservative management were statistically similar.

**10.3: Table 4: Objective 1 – the Univariate analysis of the factors associated with adverse perinatal outcomes in women who underwent aggressive versus conservative management of early-onset PES at K.N.H, 2014-2019**

Sociodemographic characteristics		Total N= 453	Perinatal adverse outcomes  N =149	No perinatal adverse outcomes  n= 302	OR 95% (CI)
Age category	≤30 years	243 (53.8%)	81 (54.4%)	162 (53.6%)	1
	>30 years	209 (46.2%)	69 (46.0%)	140 (46.4%)	1.08 (0.77 to 1.50)
Marital status	Single/Divorced	68 (15.0%)	23 (15.3%)	45 (14.9%)	1
	Married	384 (85.0%)	127 (84.7%)	257 (85.1%)	0.99 (0.63 to 1.57)
Education	None/Primary	228 (50.4%)	75 (50.0%)	153 (50.7%)	1
	Secondary	143 (31.6%)	45 (30.0%)	98 (32.5%)	1.05 (0.64 to 1.74)
	Tertiary	81 (17.9%)	30 (20.0%)	51 (16.9%)	1.07 (0.65 to 1.77)
Occupation	Unemployed/student	228 (50.4%)	121 (53.6%)	107 (47.3%)	1
	self-employed	143 (31.6%)	64 (28.3%)	79 (35.0%)	1.06 (0.68 to 1.66)
	formal employed	81 (18.0%)	41 (18.1%)	40 (17.7%)	0.99 (0.68 to 1.44)
Religion	Christian	448 (99.1%)	150 (100%)	298 (98.7%)	-
	Muslim	4 (0.9%)	0 (0.0%)	4 (1.3%)	

In table 4 above, in the univariate analysis, age, marital status, education, occupation and religion had no association with adverse perinatal outcomes.

**10.4 : Table 5:Objective 1 –Univariate analysis of the clinical factors associated with adverse perinatal outcomes of women on aggressive versus conservative management of early-onset PES at K.N.H, (2014-2019)**

Clinical characteristics		Total N= 452	No perinatal adverse outcomes n= 302	Adverse Perinatal outcomes N =150	OR (95% CI)
Management	Conservative	226 (50%)	161 (71.2%)	65 (28.8%)	1
	Aggressive	226 (50%)	141 (62.4%)	85 (37.6%)	1.49 (1.01 to 2.21)
Parity	Primiparous	140 (30.9%)	91 (65.0%)	49 (35.0%)	1
	Previous miscarriage	63 (13.9%)	39 (61.9%)	24 (38.1%)	1.14 (0.62 to 2.11)
	1 or more previous viable pregnancy	249 (55.1%)	172 (69.1%)	77 (30.9%)	0.83 (0.54 to 1.29)
Gravidity	Primigravida	92 (20.6%)	61 (66.3%)	31 (33.7%)	1
	Multigravida	355 (79.4%)	239 (67.3%)	116 (32.7%)	0.96 (0.59 to 1.55)
Gestation in weeks	Mean (SD)	30 .3 (4.7)	30.6 (4.7)	29.8 (4.5)	0.96 (0.92 to 1.01)
Duration of admission	<14 days	287 (63.5%)	198 (69.0%)	89 (31.0%)	1
	>14 days	165 (36.5%)	104 (63.0%)	61 (36.9%)	1.30 (0.87 to 1.95)

In table 5 above, on univariate analysis, babies born to women on aggressive management had a 1.5 times higher odds of developing adverse perinatal outcomes than babies born to women on

conservative management with a OR of 1.49 , 95%CI of (1.01 to 2.21) which was statistically significant.

Parity, gravidity, gestation in weeks, and duration of admission of the women was not associated with the risk of adverse perinatal outcomes in conservative versus aggressive management of early-onset PES.

**10.5: Table 6: Objective 2 – Univariate analysis of the factors associated with adverse maternal outcomes among women on aggressive versus conservative management of early-onset PES at K.N.H, (2014-2019)**

Clinical characteristics		Total N= 452	No adverse maternal outcome n= 403	Adverse Maternal outcome N =49	OR (95% CI)
Management	Conservative	226 (50%)	211 (93.4%)	15 (6.6%)	1
	Aggressive	226 (50%)	192 (84.9%)	34 (15.0%)	2.49 (1.31 to 4.72)
Parity	Primiparous	140 (31.0%)	121 (86.4%)	19 (13.6%)	1
	Previous miscarriage	63 (13.9%)	57 (90.5%)	6 (9.5%)	0.67 (0.25 to 1.77)
	1 or more previous viable pregnancy	249 (55.1%)	225 (90.4%)	24 (9.6%)	0.68 (0.36 to 1.29)
Gravidity	Primigravid	92 (20.6%)	84 (91.3%)	8 (8.7%)	1
	Multi gravid	355 (79.4%)	315 (88.7%)	40 (11.3%)	1.33 (0.60 to 2.96)
Duration of admission	<14 days	287 (63.5%)	253 (88.2%)	34 (11.9%)	1
	>14 days	165 (36.5%)	150 (90.9%)	15 (9.1%)	0.74 (0.39 to 1.41)
Gestation in weeks	Mean (sd)	30 .3 (4.7)	30.3 (4.7)	30.4 (4.9)	1.00 (0.94 to 1.07)

In table 6 above, on univariate analysis, women who underwent aggressive management had a 2.5 times greater odds of developing adverse maternal outcomes than those who underwent conservative management of early-onset PES. OR of 2.49 and 95% CI (1.31-4.72)

Parity, gravidity, duration of admission and gestation (in weeks) was not associated with a risk of adverse maternal outcomes in women who underwent aggressive versus conservative management of early-onset PES.

**10.6: Table 7: Objective 3: Mean ( $\pm$  SD) prolongation of Pregnancy(days) in women who underwent aggressive versus conservative management of early-onset PES at K.N.H (2014-2019)**

	<b>Conservative</b>	<b>Aggressive</b>	<b>Mean Difference (CI of difference)</b>	<b>p-value</b>
<b>Mean<math>\pm</math>SD</b>			14.6 (12.5- 16.8)	<b>&lt;0.001</b>
	16.4 $\pm$ 16.6	1.7 $\pm$ 1.7		

In table 7 above, the mean(standard) prolongation of pregnancy was 16.4 (16.6) with conservative management compared to 1.7(1.7) in aggressive management of early-onset PES, with a p-value of < 0.001 which is highly statistically significant.



**10.7: Table 8:Multivariate analysis of the factors associated with adverse perinatal outcome in women who underwent aggressive versus conservative management of early-onset PES at K.N.H, 2014-2019.**

Clinical characteristics		OR (95% CI)	AOR (95%CI)
Management	Conservative	1	1
	Aggressive	1.49 (1.01 to 2.21)	1.43 (0.95 to 2.15)
Parity	Primiparous	1	1
	Previous miscarriage	1.14 (0.62 to2.11)	1.12 (0.59 to 2.12)
	1 or more previous viable pregnancy	0.83 (0.54 to 1.29)	0.76 (0.46 to 1.25)
Gravidity	Primigravid	1	1
	Multi gravid	0.96 (0.59 to 1.55)	0.77 (0.43 to 1.35)
Duration of admission	<14 days	1	
	>14 days	1.30 (0.87 to 1.95)	1.35 (0.89 to 2.06)
Gestation in weeks		0.96 (0.92 to 1.00)	0.97 (0.93 to 1.01)

In table 8 above, on multi-variate analysis, babies born to women who underwent aggressive management had a 1.4 times greater odds of developing adverse perinatal outcomes than babies born to women on conservative management with an OR of 1.43, 95% C/I of (0.95-2.15) which was not statistically significant .

Therefore, in the multivariate analysis, management, parity, gravidity, duration of admission and gestational weeks were not associated with adverse perinatal outcomes

**10.8: Table 9: Multivariate analysis of the factors associated with adverse maternal outcomes in women who underwent aggressive versus conservative management of early-onset PES at K.N.H, 2014-2019.**

Clinical characteristics		UOR 95%(CI)	AOR (95%CI)
Management	Conservative	1	1
	Aggressive	2.49 (1.31 to 4.72)	2.39 (1.24 to 4.60)
Parity	Primiparous	1	1
	Previous miscarriage	0.67 (0.25 to 1.77)	0.59 (0.31 to 1.35)
	1 or more previous viable pregnancy	0.68 (0.36 to 1.29)	0.64 (0.31 to 1.35)
Gravidity	Primigravid	1	1
	Multi gravid	1.33 (0.60 to 2.96)	1.15 (0.46 to 2.87)
Duration of admission	<14 days	1	1
	>14 days	0.74 (0.39 to 1.41)	0.75 (0.94 to 1.46)
Gestation in weeks		1.00 (0.94 to 1.07)	1.03 (0.94 to 1.08)

In table 9, on multi-variate analysis, aggressive management was associated with 2.4 times greater odds of developing adverse maternal outcomes compared with conservative management of early-onset PES with a 95% C/I of (1.24-4.60) which was statistically significant.

In multi-variate analysis, the parity, gravidity, duration of admission and gestation (in weeks) were not associated with the risk of adverse maternal outcomes in women on aggressive versus conservative management of early onset PES.

## 11.0: Discussion

This study sought to determine the risk of adverse perinatal and maternal outcomes, and the mean prolongation of pregnancy in women undergoing conservative versus aggressive management of early-onset PES at KNH.

In univariate analysis, babies born to women on aggressive management had a 1.5 times greater odds of developing adverse perinatal outcomes than babies born to women on conservative management with an O.R of 1.49, 95% C/I(1.01 to 2.21) which was statistically significant. On multivariate analysis, we found non-statistically significantly 1.4 times greater odds of adverse perinatal outcomes in the A/M arm compared to the C/M arm. O.R of 1.43, 95% C/I(0.95 to 2.15) which was not statistically significant. This is comparable to a study by Sibai et al, that had perinatal mortality of 0% for both groups. (26) In another study by Sarsam et al, the prevalence of perinatal mortality was lower in the C/M arm i.e. 11.43% versus 25.64% in A/M arm.(7) Both findings were not statistically significant in both studies which was comparable to our study.

This study has shown that on univariate analysis, women who underwent aggressive management had a 2.5 times greater odds of developing adverse maternal outcomes than those who underwent conservative management of early-onset PES with an OR of 2.48, 95% C/I (1.31 to 4.72) which was statistically significant. On multivariate analysis, aggressive management was associated with 2.4 times greater odds of developing adverse maternal outcomes compared with conservative management of early-onset pre-eclampsia with severe features (PES) with an OR of 2.39, 95% C/I(1.24 to 4.60) which was statistically significant. This finding is comparable to the previous studies that have shown that aggressive management of early-onset PES is associated with an increased risk of adverse maternal outcomes as compared to conservative management.

In a study by Sarsam et al, the prevalence of eclampsia was 2.86% in the conservative management arm which was lower compared to 17.95% in the aggressive management arm.(7) In the same study, pulmonary edema was noted to be at 2.86% in the conservative management group compared with 7.69% in the aggressive arm. Likewise, in the MEXPRES Latin Study, the

incidence of HELLP was noted to be 13.5% in conservative management arm versus 16% in the aggressive management arm (6). All these comparable studies are similar to the present study. However, they differ in terms of being carried out in different geographic regions and racial groups.

This study has also shown that women on conservative management had a mean(standard deviation) prolongation of pregnancy of 16.4(16.6) (in days) compared with those on aggressive management. This is comparable to the previous studies that have shown a similar mean(standard deviation) prolongation of pregnancy(in days) as a result of conservative management of early-onset PES: studies done by Sibai et al, Odendaal et al, and Sarsam et al, had a mean(standard deviation) prolongation of pregnancy of 15.4(4-36), 7.1 and 9.2(3-8) respectively.(26)(14)(7)

## **12.0:Conclusion:**

This study has shown that aggressive management was associated with 2.4 times greater odds of developing adverse maternal outcomes compared with conservative management of early-onset PES. The risk of adverse perinatal outcomes was found to be non-statistically significantly greater in the A/M arm compared to the C/M arm of early-onset PES. In addition, conservative management of early-onset PES had a mean(standard deviation) prolongation of pregnancy of 16.4(16.6) days.

## **13.0:Recommendations:**

1. Pregnant women with early-onset PES eligible for conservative management should be offered under close monitoring and advised that it takes on average two weeks from admission to delivery with a decreased odds of risk maternal adverse outcomes.
2. The study results can be instrumental in informing policy and local guidelines on management of early-onset PES.
3. In addition, a prospective study with a prolonged follow-up period of newborns should be conducted in the future to provide a better insight on the outcomes.

## **14.0:Study Limitations & Strengths:**

### **14.1:Limitations**

There were challenges with data completeness. Some of the pregnant women that met the inclusion criteria were excluded because of missing data and others were excluded because they were managed at KNH initially but chose to deliver elsewhere so could not be assessed for maternal and perinatal outcomes.

### **14.2:Strengths**

- This was a first study on this specific topic to be done locally; therefore it will be instrumental in informing policy and local guidelines.
- The large sample size(**226 per arm**) was an added advantage as it allows generalization of the results.

## 15.0 Study Timelines

*Figure 3: Study Timeline*

	2019						2020		
	Jan – Feb	March - Apr	May - June	July - Aug	Sept - Nov	Dec	Jan – March	Mar - Apr	May
Concept Development									
Proposal Development									
Ethics Approval									
Data Collection									
Results Presentation									
Final Report preparation and approval									
Results Dissemination									

## 16.0 REFERENCES

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## 17.0 APPENDICES

### 17.1: APPROVAL FROM KNH-UON ERC

0993599. # System No \*

To pay 1500/-  
for Access to Patients  
Records  
code 4020  
Ball 198706



UNIVERSITY OF NAIROBI  
COLLEGE OF HEALTH SCIENCES  
P O BOX 19676 Code 00202  
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KENYATTA NATIONAL HOSPITAL  
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Ref: KNH-ERC/A/103

18<sup>th</sup> March 2020

Dr. Zainab Dida Golicha  
Reg. No.H58/7080/2017  
Dept. of Obstetrics and Gynaecology  
School of Medicine  
College of Health Sciences  
University of Nairobi

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Dear Dr. Dida

**RESEARCH PROPOSAL –OUTCOMES OF EXPECTANT MANAGEMENT OF EARLY-ONSET PRE-ECLAMPSIA WITH SEVERE FEATURES AT KENYATTA NATIONAL HOSPITAL: A RETROSPECTIVE DESCRIPTIVE COHORT STUDY (P989/12/2019)**

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 18<sup>th</sup> March 2020 – 17<sup>th</sup> March 2021.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

Yours sincerely,



PROF. M. L. CHINDIA  
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN  
The Director, CS, KNH  
The Chairperson, KNH- UoN ERC  
The Assistant Director, Health Information, KNH  
The Dean, School of Medicine, UoN  
The Chair, Dept. of Obstetrics and Gynaecology, UoN  
Supervisors: Prof. Zahida Qureshi(UoN), Dr. Alfred Osoti(UoN)

## 17.2: APPENDIX 2: STUDY TOOL

Record No.....File IP No.....

Before proceeding to extract the data, ascertain eligibility using the following eligibility checklist.

- PES with severe features*
- Gestation between 24 and 34 weeks*
- Singleton pregnancy*
- Fetus viable,*
- No maternal complications such as Malaria, cardiac problems, renal problems, HELLP*

If all the four are met, proceed with data collection

### A. Demographic Data

1. Age in years \_\_\_\_\_
2. Marital status
  - a. Single [ ]
  - b. Married [ ]
  - c. Divorced [ ]
  - d. Widow [ ]
3. Level of Education

- a. *No formal Education* [     ]
- b. *Primary* [     ]
- c. *Secondary* [     ]
- d. *college/University* [     ]

4. Occupation

- a. *Unemployed* [     ]
- b. *Student* [     ]
- c. *Self-employed* [     ]
- d. *Formal employment* [     ]

5. Religion

- a. *Christian* [     ]
- b. *Muslim* [     ]
- c. *Hindu* [     ]
- d. *Others (state) .....*

6. What is the resident county? \_\_\_\_\_

7. What is the mother's parity? \_\_\_\_\_ + \_\_\_\_\_

8. What is the mother's gravidity \_\_\_\_\_

9. What is the gestation (**on admission**)

a. LMP ..... EDD.....

b. By Dates .....weeks ..... days or By Ultrasound .....weeks, .....days.

10. Date of Admission ..... Date of Delivery .....

**B. Adverse Perinatal Outcomes in aggressive versus conservative management**

11. Birth weight (in grams) \_\_\_\_\_

Identify in the table the reported perinatal outcomes

	<b>Perinatal Outcomes</b>	<b>Present</b>	<b>Absent/Not Reported</b>
12.	Non-reassuring fetal status		
13.	5 minute Apgar Score		
14.	Respiratory Distress/Asphyxia		
15.	Intrauterine growth restriction		
16.	Baby admitted to newborns unit		
17.	Perinatal mortality		

**C. Adverse Maternal Outcomes in aggressive versus conservative management**

Identify in the table the reported adverse maternal outcomes

	<b>Adverse Maternal Outcome</b>	<b>Present</b>	<b>Absent/Not Reported</b>
18.	HELLP		
19.	Eclampsia		
20.	Renal impairment		
21.	Pulmonary Edema		
22.	Maternal mortality		
23.	Neurologic deficit		

**D. Factors associated with adverse maternal and perinatal outcomes**

Abstract the information from the patient's file accordingly

<b>Factor</b>	<b>Yes</b>	<b>No</b>
Maternal Anemia		
Maternal renal disease		
Uncontrolled blood pressure		