

The use of low-dose aspirin for the prevention of hypertensive disorders of pregnancy in a Sub-Saharan country

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| Submission date 19/08/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 23/08/2024 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 22/08/2024 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

In South Africa, the level of hypertensive (high blood pressure) disorders of pregnancy remains high. The Saving Mothers executive summary report (2020-2022) states that hypertensive disorders of pregnancy are the third leading cause of deaths occurring to mothers during and after pregnancy, accounting for 14.7% of all deaths in SA and the impact of COVID-19 pandemic led to current status.

Therefore, this study aims to determine the effect of low-dose aspirin in pregnant women of African ancestry and its association with hypertensive disorders of pregnancy. The study evaluates aspirin as a treatment for primary prevention of hypertensive disorders, including preeclampsia in all pregnant women considered to be at high risk following first -three months of pregnancy. Also , to evaluate the effects of aspirin on the occurrence in early (delivery before 34 weeks of pregnancy) preeclampsia, the rate of unexpected growth of small size baby in the womb, loss in the womb during delivery and after delivery, placental separation before delivery and admission to neonatal intensive care as secondary prevention.

Who can participate?

Pregnant women, between 12 to 20 weeks of pregnancy aged 18 years and above and that are considered to be at risk of hypertensive disorders of pregnancy.

What does the study involve?

The study involves low-dose aspirin intake (162mg) daily at night from the day of recruitment until 36 of pregnancy, or treatment as usual, thereafter followed up until delivery.

What are the possible benefits and risks of participating?

The benefits of participating in the study was the reduced occurrence of hypertensive disorders of pregnancy involving preeclampsia and gestational hypertension.

Where is the study run from?

University of Kwa-Zulu Natal college of health sciences (South Africa). The study was conducted in a regional hospital in KwaZulu-Natal province of South Africa.

When is the study starting and how long is it expected to run for?

The study commenced in March 2019 and ended in April 2024 It could not continue due to COVID-19 pandemic and KwaZulu-Natal floods that affected the entire recruitment.

Who is funding the study?

University of Kwa-Zulu Natal college of health sciences and the Women's health and HIV research unit (South Africa)

Who is the main contact?

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Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

BREC BFC163/19

Study information

Scientific Title

The effect of low dose aspirin in the prevention of hypertensive disorders of pregnancy: A parallel open labelled randomized controlled trial

Acronym

ELDAPPE study

Study objectives

Does administration of low dose aspirin result in a decrease in frequency of hypertensive disorders when prescribed in early pregnancy

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 10/09/2020, Biomedical Research Ethics Committee, University of KwaZulu-Natal (Biomedical Research Ethics Committee Research Office, UKZN Private Bag X 54001 Durban 4000, Durban, 4001, South Africa; +27 2604709; BREC@ukzn.ac.za), ref: BFC136/19

Study design

Single centre interventional open labelled parallel randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention, Treatment

Health condition(s) or problem(s) studied

Prevention of hypertensive disorders of pregnancy, in particular, pre-eclampsia

Interventions

This was a single center interventional, open labelled randomized controlled trial. The study was conducted at a regional hospital in South Africa to evaluate the effectiveness of low-dose aspirin (LDA) in preventing HDP in women of African ancestry. Normotensive pregnant women aged ≥ 18 years, with singleton pregnancies between 12 and 20 weeks of gestation, were recruited from the study site's antenatal clinic. The intention was to recruit between 12-16 weeks gestation. The initial intention was to recruit 970 participants, with equal numbers assigned to the intervention and control groups. Due to recruitment challenges, 423 participants were eventually enrolled. The initial sample (970), size was statistically obtained based on hypertensive disorder incidence (12%) in South African context. A simple random sampling was conducted to select women based on the inclusion and exclusion criteria.

Randomization and Grouping: Participants were randomly assigned to either the intervention group (n=209) or the control group (n=214) using a simple 1:1 allocation ratio. As such randomisation occurred based on a coin toss with one participant allocated to the representation of the coin face and the following participant that was recruited was allocated to the alternate group. The intervention group received low-dose aspirin (Ecotrin, 162 mg daily) monthly supply, while the control group received standard antenatal care without aspirin.

Intervention: LDA was initiated between 12 and 20 weeks of gestation and continued until 36 weeks. Participants in the intervention group were instructed to take 162 mg of LDA nightly. Compliance was monitored through "pill counts" and bi-weekly telephonic interviews

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Aspirin [Ecotrin]

Primary outcome(s)

Incidence of hypertensive disorders of pregnancy including pre-eclampsia (both early and late) and gestational hypertension (defined as a systolic blood pressure (SBP) ≥ 140 mm Hg and/or diastolic blood pressure (DBP) ≥ 90 mm Hg after 20 weeks of gestation in a woman who was at baseline normotensive) measured using a sphygmomanometer

Key secondary outcome(s)

1. Gestational age measured at delivery
2. Baby weight measured in kg at birth
3. Infant outcome (dead or alive) during antenatal period

Completion date

01/04/2024

Eligibility

Key inclusion criteria

1. Pregnant women that is 18 years and older
2. Pregnant women and women with one or more risk factors for hypertensive disorders of pregnancy, such as a previous history of unexplained pregnancy loss,
3. Previous history or family history of hypertensive disorders,

Participant type(s)

Population

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

99 years

Sex

Female

Total final enrolment

423

Key exclusion criteria

1. Women on aspirin or other antiplatelet agents
2. Women with multiple pregnancies

3. Women with fetal abnormalities, diabetes, hypertension, anemia, or other chronic diseases.
4. women with contraindications to aspirin use
5. Women who decline entry to the study

Date of first enrolment

01/05/2021

Date of final enrolment

31/01/2024

Locations

Countries of recruitment

South Africa

Study participating centre**Prince Mshiyeni Memorial Hospital**

P/Bag X07 Mobeni 4060

Mangosuthu Highway

Durban

South Africa

4001

Sponsor information

Organisation

University of KwaZulu-Natal

ROR

<https://ror.org/04qzfn040>

Funder(s)

Funder type

University/education

Funder Name

College of Health Sciences, University of KwaZulu-Natal

Alternative Name(s)

University of KwaZulu-Natal, College of Health Sciences, UKZN's College of Health Sciences, College of Health Sciences, College of Health Sciences - UKZN, University of KwaZulu-Natal College of Health Sciences, UKZN's CHS, CHS, UKZN CHS

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

South Africa

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated and analysed during the current study are not expected to be made available as there is ongoing study related to the work, however where data needs to be made available as it pertains to a particular outcome that is being published, that data will be made available for transparency

IPD sharing plan summary

Data sharing statement to be made available at a later date