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Low-dose aspirin in the prevention of preeclampsia

Submission date
27/04/2022

Recruitment status
No longer recruiting

Registration date
19/05/2022

Overall study status
Completed

Last Edited
29/11/2022

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Preeclampsia is a condition that can occur during pregnancy where there is a sudden rise in blood pressure. It typically affects 2%–5% of pregnant women and is one of the leading causes of maternal and perinatal illness and death. The exact nature of the primary event causing preeclampsia is not known. There is now good evidence that intake of low dose aspirin during pregnancy reduces the risk of pre-eclampsia. Therefore this study is developed to find out the role of aspirin in preeclampsia, the knowledge of which is expected to be used for the prevention of preeclampsia.

Who can participate?
Pregnant women aged 18 years or more who are at high risk for developing preeclampsia

What does the study involve?
Participants will be asked some questions to enrol on the study. Participants are randomly allocated to take 75 mg of aspirin after lunch on a full stomach or to not take aspirin. All participants will be followed up at 19-24 weeks, 32-34 weeks and 36 weeks of gestation and weekly up to delivery. During follow up their blood pressure will be carefully measured and urine tests will be done. Aspirin will be stopped either 36 weeks of pregnancy or when delivery occurs or when preeclampsia is diagnosed.

What are the possible benefits and risks of participating?
Aspirin can reduce the incidence of preeclampsia and also reduce the risk of gestational high blood pressure, oligohydramnios (too little amniotic fluid), preterm labor, placental abruption, antepartum/postpartum haemorrhage (bleeding), low birth weight, preterm birth, small for gestational age, intrauterine death, stillbirth, and NICU admission. Aspirin does not have any major risks except digestive upset.

Where is the study run from?
BIRDEM-2 General Hospital (Bangladesh)

When is the study starting and how long is it expected to run for?
February 2018 to February 2020

Who is funding the study?
Beacon Pharmaceuticals Ltd (Bangladesh)

Who is the main contact?
Dr Shapla Khatun
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BIRDEM/IRB/2019/186

Study information

Scientific Title
Low-dose aspirin in the prevention of preeclampsia: a randomised control study

Acronym
A-preeclampsia

Study objectives

Low-dose aspirin can lower the development of preeclampsia in pregnant women who are at high risk of developing preeclampsia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/02/2019, Institutional Review Board (IRB) of BIRDEM General Hospital (Room 323, Ibrahim Memorial Diabetes Centre,122, Kazi Nazrul Islam Avenue, Dhaka-1006, Bangladesh; +880 (0)8616641-50, +880 (0)9661551-60; academy®dab-bd.org), ref: BIRDEM/IM3/2019M6

Study design
Randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Preeclampsia

Interventions
Randomization will be done through a lottery with closed envelopes:
1. Aspirin group: take 75 mg of aspirin after lunch on a full stomach
2. Control group: do not take aspirin

All participants will be followed up at 24, 32 and 36 weeks then weekly until delivery.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Aspirin

Primary outcome measure

Occurrence of preeclampsia measured by measuring blood pressure (following standard procedures) and proteinuria (by dipstick test) at the time of delivery

Secondary outcome measures
Maternal:
1. Gestational hypertension (HTN) measured by measuring blood pressure (following standard procedures) at the time of delivery
2. Oligohydramnios measured using the amniotic fluid index (AFI) at the time of delivery.
3. Preterm labour measured by history taking and examination during each follow up (24, 32 and 36 weeks then weekly until delivery)
4. Antepartum haemorrhage (APH) measured by history taking and examination during each follow up (24, 32 and 36 weeks then weekly until delivery)

Fetal:
1. Low birth weight by measuring the weight of baby after delivery
2. Preterm birth (defined as baby born before 37 weeks)
3. Small for gestational age measured by ultrasound color Doppler during follow up
4. Intrauterine death (IUD) after 28 weeks of gestation
5. Stillbirth (death during the process of delivery)
6. Neonatal intensive care unit (NICU) admission recorded after delivery

Overall study start date
02/02/2018

Completion date
28/02/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/05/2022:
1. Maternal age ≥18 years
2. Live foetus at gestational age 12–19 weeks
3. Any one of the following criteria:
3.1. BMI ≥30 kg/m2
3.2. Pregnancy interval >10 years
3.3. Multiple pregnancy
3.4. Pregnancy assisted by ovulation-inducing drugs/in vitro fertilization
3.5. Pregnant women with medical disorders, e.g. chronic hypertension, hyperglycaemia in pregnancy, autoimmune disease (e.g. antiphospholipid syndrome [APS], systemic lupus erythematosus [SLE])
3.6. Previous history of gestational hypertension, pre-eclampsia or eclampsia
3.7. Previous history of intrauterine growth restriction (IUGR), intrauterine death or stillbirth
3.8. Family history (mother and/or sister) of hypertension, gestational hypertension or pre-eclampsia

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Previous inclusion criteria:
1. Nulliparous

2. Maternal age ≥16 years and ≥35 years
3. BMI ≥30 kg/m²
4. Live foetus at gestational age 12 weeks – 19 weeks
5. Pregnancy interval >10 years
6. Multiple pregnancy
7. Pregnancy assisted by ovulation-inducing drugs/in vitro fertilization
8. Pregnant women with medical disorders: chronic HTN, hyperglycaemia in pregnancy, thyroid disorder, autoimmune disease - antiphospholipid syndrome (APS), systemic lupus erythematosus (SLE)
9. Previous history of gestational HTN, preeclampsia (PE), eclampsia
10. Previous history of intrauterine growth restriction (IUGR), IUD, stillbirth
11. Family history of HTN, gestational HTN, PE (mother and/or sister)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
230

Total final enrolment
200

Key exclusion criteria
Current exclusion criteria as of 26/05/2022:
1. Allergic to aspirin
2. Peptic ulcer disease
3. Mental disease
4. Treatment with antifolate drugs (antiepileptics, methotrexate)
5. Patient will not give consent to participate

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Previous exclusion criteria:
1. Allergic to aspirin
2. Peptic ulcer disease
3. Pregnant women who are at risk of developing PE but who have renal failure, hepatic failure, cardiac failure and hematological disorder
4. Mental disease
5. Treatment with antifolate drugs (antiepileptics, methotrexate)
6. Patient will not give consent to participate

Date of first enrolment
05/02/2019

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Bangladesh

Study participating centre
BIRDEM
Department of Obstetrics & Gynae
BIRDEM-2 General Hospital
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Sponsor information

Organisation
Beacon Pharmaceuticals Ltd

Sponsor details
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Sponsor type
Industry

Website
https://www.beaconpharma.com.bd

Funder(s)

Funder type
Industry

Funder Name
Beacon Pharmaceuticals Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
15/05/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Shapla Khatun (dr.shapla_islam@yahoo.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			29/11/2022	No	No