

Low-dose aspirin in the prevention of preeclampsia

Submission date 27/04/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/05/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/11/2022	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

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

Dhaka
Bangladesh

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Sponsor information

Organisation

Beacon Pharmaceuticals Ltd

Funder(s)

Funder type

Industry

Funder Name

Beacon Pharmaceuticals Ltd

Results and Publications

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