

# Low-dose aspirin in the prevention of preeclampsia

<b>Submission date</b> 27/04/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/05/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/11/2022	<b>Condition category</b> 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  
Dr.shapla\_islam@yahoo.com

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Shapla Khatun

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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  $\geq 18$  years
2. Live foetus at gestational age 12–19 weeks
3. Any one of the following criteria:
  - 3.1. BMI  $\geq 30$  kg/m<sup>2</sup>
  - 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  $\geq 16$  years and  $\geq 35$  years
3. BMI  $\geq 30$  kg/m<sup>2</sup>
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

Dhaka

Bangladesh

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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?
<a href="#">Protocol file</a>			29/11/2022	No	No