

# Low dose aspirin with an early screening test for pre-eclampsia and fetal growth restriction

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<b>Registration date</b> 10/02/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2020	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Pre-eclampsia is a condition that affects 2-8% of pregnancies. Previous studies have shown that aspirin can reduce the occurrence of pre-eclampsia in women with known risk factors but we know little for low risk populations. This study aims to assess if it is beneficial in terms of effectiveness and patient acceptability to routinely prescribe low dose aspirin to low risk women on the basis of a positive early pregnancy screening test for pre-eclampsia and fetal growth restriction. The specific aims of this study are:

1. Number of eligible women who agree to participate in the study.
2. Adherence to the study methodology
3. Number of women in whom it was possible to get first trimester abdominal uterine artery Doppler examination
4. Number of women with completed screening test who are issued the screening result on time

### Who can participate?

Women who are expecting their first baby, less than 14 weeks pregnant at their first visit, not on aspirin

### What does the study involve?

500 first time mothers with low-risk pregnancies will be randomly allocated to one of three groups from early pregnancy:

Group 1 will receive 75mg of aspirin until 36 weeks

Group 2 will not receive aspirin

Group 3 will receive 75mg of aspirin until 36 weeks only if they screen positive using the Fetal Medicine Foundation (FMF) early pregnancy screening test for pre-eclampsia and fetal growth restriction prediction. If this screening test is negative, group 3 will not receive aspirin.

All participants will undergo these first trimester screening tests but the results will only be given for group 3.

### What are the possible benefits and risks of participating?

Benefits include detailed scans performed of the baby in the first and second trimester of pregnancy as well as monitoring of blood pressure. Mothers involved in the study will be contributing to a study which has the potential to significantly reduce the occurrence of

pregnancy complications such as pre-eclampsia and fetal growth restriction which risks the lives of mothers and babies worldwide. Studies have shown that low dose aspirin appear to be safe for mother and baby, it is a medication frequently used by mothers who are at high risk of developing pre-eclampsia.

Where is the study run from?

The study will run from the National Maternity Hospital, Coombe Maternity Hospital and Rotunda Maternity Hospital, Dublin, Ireland.

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

The trial is starting in February 2014 and is expected to run for two years.

Who is funding the study?

Perinatal Ireland Consortium (Ireland)

Who is the main contact?

Professor Fionnuala McAuliffe  
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## Contact information

### Type(s)

Scientific

### Contact name

Prof Fionnuala McAuliffe

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## Additional identifiers

### EudraCT/CTIS number

2013-004241-17

### IRAS number

### ClinicalTrials.gov number

NCT03674606

### Secondary identifying numbers

TEST\_PILOT\_V1

# Study information

## Scientific Title

An open-label randomized-controlled trial of low dose aspirin with an early screening test for pre-eclampsia and fetal growth restriction: a pilot study

## Study objectives

The hypothesis of this study is to assess if it is beneficial in terms of efficacy and patient acceptability to routinely prescribe low dose aspirin to nulliparous low risk women compared with test indicated aspirin on the basis of a positive early pregnancy screening test for pre-eclampsia and fetal growth restriction.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

National Maternity Hospital, Dublin, Ireland, 11/11/2013

## Study design

Multicentre randomized controlled open-labelled pilot trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

GP practice

## Study type(s)

Prevention

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Pregnancy/pre-eclampsia/fetal growth restriction

## Interventions

Following assessment for study eligibility at time of antenatal booking in the first trimester, women will undergo computer-generated randomisation to one of 3 antenatal management protocols:

1. Aspirin therapy 75mg daily commencing after a satisfactory 1st trimester assessment, followed by a mid-trimester assessment and routine antenatal care thereafter (routine aspirin arm)
2. No aspirin therapy with 1st trimester assessment, mid-trimester assessment and routine antenatal care thereafter (control arm)

3. Postponement of decision regarding aspirin therapy until availability of the Fetal Medicine Foundation screening result for pre-eclampsia risk at time of 1st trimester assessment, with immediate commencement of aspirin 75mg daily in the screen positive subgroup, set at a false positive rate of 5% (screen & treat arm)

Assessment at the first trimester visit will include:

1. Assessment of blood pressure
2. Ultrasound scan: uterine artery doppler measurements
3. Blood tests: placental biomarkers to determine pre-eclampsia risk

The routine aspirin arm and those with a screen positive in the screen and treat arm will receive Aspirin 75mg from first trimester until 36 weeks of pregnancy and all participants will be asked to return for a visit at 20-22 weeks of pregnancy which will involve:

1. Blood pressure
2. Repeating the blood tests for placental biomarkers
3. Performing an ultrasound of fetal anatomy and uterine artery doppler assessment

Women will then attend for routine antenatal care until delivery

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Aspirin

### **Primary outcome measure**

1. Proportion of eligible women who agree to participate in the pilot study. This will be calculated by the % of women who agree to study participation out of all those eligible women who were approached for study participation after written consent has been obtained in the first trimester.
2. Compliance with the study protocol. This will be measured at 20 week with a compliance questionnaire for those prescribed aspirin 75mg.
3. Proportion of women in whom it was possible to obtain first trimester trans-abdominal uterine artery Doppler examination. This will be assessed at the first trimester visit.
4. Proportion of women with completed screening test who are issued the screening result on time. This will be assessed as the % of women who received a result of the screening test within one week of having the test performed in the screen and treat group (group 3)

### **Secondary outcome measures**

1. Rate of pre-eclampsia. This is defined as those with BP 140/90 with +1 proteinuria at any time in pregnancy.
2. Rate of fetal intrauterine growth restriction (IUGR), defined as birth-weight <10th centile for gestational age
3. Spontaneous or iatrogenic delivery at <34 and < 37 completed weeks.
4. Rate of admission to the neonatal intensive care unit
5. Rate of placental abruption, any reported death (stillbirth, neonatal or infant death) and small for gestational age infants
6. Patient acceptability will be assessed with a questionnaire at 34 weeks gestation

**Overall study start date**

01/02/2014

**Completion date**

13/04/2016

## Eligibility

**Key inclusion criteria**

1. Women who are in their first pregnancy
2. Women who are able to speak and read English so that they can provide consent to be included in the study
3. Women who have a singleton pregnancy below 14 weeks

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

500 pregnant women

**Total final enrolment**

546

**Key exclusion criteria**

1. Presence of fetal abnormality at the time of the first trimester scan
2. Women with known risk factors for pre-eclampsia or growth restricted babies who may already be on Aspirin for this reason
3. Women already taking part in another study
4. Women who cannot take Aspirin
5. Women aged under 18 years

**Date of first enrolment**

08/05/2014

**Date of final enrolment**

01/02/2016

## Locations

**Countries of recruitment**

Ireland

**Study participating centre**  
**UCD Obstetrics & Gynecology**  
Dublin  
Ireland  
Dublin 2

## **Sponsor information**

### **Organisation**

University College Dublin (Ireland)

### **Sponsor details**

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### **Sponsor type**

University/education

### **Website**

<http://www.ucd.ie/medicine/ourresearch/researchcentres/ucdclinicalresearchcentre/>

### **ROR**

<https://ror.org/05m7pjf47>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

Perinatal Ireland (Ireland)

## **Results and Publications**

Publication and dissemination plan

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

### **Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	28/07/2018		Yes	No
<a href="#">Protocol article</a>	protocol	01/07/2016	13/02/2020	Yes	No