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

Submission date
08/01/2014

Recruitment status
No longer recruiting

Registration date
10/02/2014

Overall study status
Completed

Last Edited
13/02/2020

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2013-004241-17

ClinicalTrials.gov (NCT)
NCT03674606

Protocol serial number
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

Study type(s)
Prevention

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 satisfactory1st 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(s)
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)

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Research organisation

Funder Name
Perinatal Ireland (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/07/2018		Yes	No
Protocol article	protocol	01/07/2016	13/02/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes