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Early aspirin to improve pregnancy outcome in diabetes

Submission date
02/12/2014

Recruitment status
No longer recruiting

Registration date
16/12/2014

Overall study status
Completed

Last Edited
16/12/2014

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Diabetes in a medical condition where the amount of sugar in the blood is too high. This can be the result of the body not making any insulin (type 1 diabetes) or not making enough or poorly functioning insulin (type 2 diabetes). Pre-existing diabetes can cause a number of health-related problems for pregnant women. They are, for example, at a higher than usual risk of developing the potentially dangerous condition pre-eclampsia. Pre-eclampsia is thought to be the result of the placenta not working properly, putting the baby at risk of not getting enough oxygen and nutrients to grow properly. Early symptoms include high blood pressure, and passing protein in the urine. Left untreated, eclampsia can develop, a life-threatening condition for both mother and baby leading to seizures and multiple organ failure. Pre-eclampsia is known to start in early pregnancy, when the placenta first starts to develop. The role of aspirin in the prevention of pre-eclampsia has been investigated in several trials and it is thought that it may be of some benefit to some women thought to be of high risk. However, the few studies that recruited women with diabetes report conflicting results and most of them introduced aspirin too late into the pregnancy. We want to see whether aspirin therapy introduced in early pregnancy in women with pre-existing diabetes may reduce the risk of complications related to pre-eclampsia, such as placental abruption, stillbirth and eclampsia. We will test how happy patients with diabetes are to take aspirin early in pregnancy, determine how likely they are to continue to take aspirin throughout their pregnancy, and to assess the effect of the treatment on platelets, blood components responsible for clotting.

Who can participate?
Pregnant women with pre-existing diabetes.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given a single dose of aspirin each day from the first trimester until 36 weeks gestation. Those in group 2 do not receive the aspirin. We look at the number of eligible women who agree to participate, comply with the instructions of the study and complete the study. Control of blood sugar levels, kidney function and platelet function are all monitored though laboratory tests.

What are the possible benefits and risks of participating?
While use of aspirin in non-pregnant people may be associated with a slightly increased risk of bleeding, the use of a low dose as in this study has not been associated with increased risks for mum or for baby. None or very few side effects for mother or baby have been seen in large clinical trials to date. It is regarded as a safe drug to take in pregnancy up until 36 weeks at a low dose and is routinely used in 'high-risk' women without any problems. We will withdraw patients from the study if they develop a severe medical complication or if their safety is at risk. The benefit of study participation is in intensive maternal-fetal surveillance throughout the prenatal and postnatal period.

Where is the study run from?
1. Rotunda Hospital, Dublin (Ireland)
2. Coombe Women's and Infants University Hospital, Dublin (Ireland)

When is the study starting and how long is it expected to run for?
March 2013 to December 2015

Who is funding the study?
Friends of the Rotunda Hospital (Ireland)

Who is the main contact?
Dr Fionnuala Breathnach

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2014-0011332-11

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IRELAnD_PILOT_V1

Study information

Scientific Title
'IRELAnD': Investigating the Role of Early Low-dose Aspirin in preexisting Diabetes': An open-label randomized pilot study

Acronym
IRELAnD

Study objectives
The purpose of this pilot study is to determine rates of patient participation and compliance with aspirin therapy, in addition to exploration of the effect of low-dose aspirin on platelet function throughout pregnancy in this high-risk population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Maternity Hospital Research Ethics Committee (National Central Committee), 30/07/2014

Study design
Prospective, randomized, pilot study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Placental dysfunction, including preeclampsia, in pregnant women with pregestational diabetes

Interventions
Study arms:
Women with pregestational diabetes are randomized to receive aspirin 75mg or no aspirin.

Intervention:
Aspirin Acetylsalycylic Acid 75mg tablet (Nu-Seals®PA 943/6/1) once daily by oral ingestion from first trimester (initiated between 8+0 and 11+6 weeks) to 36 weeks gestation for women with pregestational diabetes mellitus (type I or II).

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Aspirin Acetylsalycylic Acid 75mg tablet (Nu-Seals®PA 943/6/1)

Primary outcome measure
1. Proportion of eligible women who agree to participate in the pilot study
2. Compliance with the study protocol, as judged by platelet function monitoring
3. Proportion of study participants who complete the study, with complete ascertainment of laboratory markers of glycaemic control, renal function and platelet function at all scheduled timepoints

Will be measured within 4 weeks of delivery of each participant (i.e. within 35 weeks of recruitment).

Secondary outcome measures
Examination, through dynamic platelet function assay, of antiplatelet effect among women with pregestational diabetes when compared with platelet function in diabetic women not taking antiplatelet therapy.

Will be measured within 4 weeks of delivery of each participant (i.e. within 35 weeks of recruitment).

Overall study start date
01/03/2014

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. All women with type I or type II diabetes of at least 6 months duration prior to conception
2. Ability to speak and read English
3. Singleton pregnancy at <12 weeks' gestational age
4. Those willing to sign voluntarily a statement of informed consent to participate in the study

Participant type(s)
Patient

Age group

Adult

Sex
Female

Target number of participants
24

Key exclusion criteria
1. Aspirin hypersensitivity (prior bronchospasm/ urticarial/ angioedema with aspirin)
2. Peptic ulcer disease
3. Known bleeding diathesis
4. Multifetal gestation
5. Severe early-onset preeclampsia in a previous pregnancy
6. Patient already on aspirin
7. Age under 18 years
8. Miscarriage prior to randomization

Date of first enrolment
16/12/2014

Date of final enrolment
16/04/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Rotunda Hospital
Dublin
Ireland

Study participating centre
Coombe Women's and Infants University Hospital
Dublin
Ireland

Sponsor information

Organisation
Royal College of Surgeons in Ireland

Sponsor details
Clinical Research Centre
123 St Stephen's Green
Dublin
Ireland
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Sponsor type
University/education

ROR
https://ror.org/01hxy9878

Funder(s)

Funder type
Charity

Funder Name
Friends of the Rotunda Hospital (Ireland)

Results and Publications

Publication and dissemination plan
The results of the IRELAND study will be published in a high quality clinical journal. Results of the pilot phase will lead to the support of a larger scale randomized controlled trial and may lead to a change in clinical practice and guideline publication on a national and international level. The responsibility for publication of the data obtained from this study lies with the study investigators. Neither the sponsor, nor any study funders, will have involvement in data collection, data review, data analyses or preparation of the publication manuscript or in the decision to submit for publication.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration