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A trial to investigate the role of the food supplement inositol in the general health of those at risk of developing gestational diabetes mellitus

Submission date
19/09/2013

Recruitment status
No longer recruiting

Registration date
31/10/2013

Overall study status
Completed

Last Edited
15/02/2018

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gestational diabetes mellitus is a form of diabetes that can occur in pregnancy. This can affect both mother and baby during the course of the pregnancy and delivery. Inositol is a food supplement which has been shown in small studies to have health benefits including reducing the incidence of gestational diabetes in those at risk of getting it. The aim of our study is to find out the possible health benefits of Inositol for women at risk. This includes finding out if they have a decreased incidence of gestational diabetes, if they have fewer complications during delivery, if their baby's weight is affected and if their baby's first few days of life is affected.

Who can participate?
Women who are 10-14 weeks pregnant and who are at risk of developing gestational diabetes due to a family history of diabetes

What does the study involve?
Participants are randomly allocated to one of two groups: the intervention group or the placebo (dummy) group. The intervention group take one tablet every day containing Inositol combined with folic acid and the placebo group take folic acid alone. They then follow standard care and be tested as routine for gestational diabetes at 26 weeks. If they have diabetes they attend the diabetes clinic and if not they follow standard care. Their pregnancy is followed until delivery. The type of delivery they have, the weight or their baby and any complications for themselves or their baby are recorded.

What are the possible benefits and risks of participating?
The benefit of participating in this study is that it may have health benefits for them. There are no expected risks in participating. Studies have not shown any side effects of Inositol at the doses we are using.

Where is the study run from?
The Coombe Women and Infant's University Hospital (Ireland)

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

Who is funding the study?
The Coombe Women and Infants University Hospital (Ireland)

Who is the main contact?
Dr Maria Farren
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Contact information

Type(s)
Scientific

Contact name
Prof Sean Daly

Contact details
Coombe Women and Infant's University Hospital
Cork Street
Dublin
Ireland
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Additional identifiers

EudraCT/CTIS number
2013-003572-12

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15-2013

Study information

Scientific Title
A randomised controlled trial to investigate the role of myoinositol and D-chiro-inositol (in physiological ratio 40:1) in the general health of those at risk of developing gestational diabetes mellitus

Study objectives
Current hypothesis as of 09/04/2014:
Inositol has been shown to have health benefits in those at risk of diabetes mellitus. We wish to

investigate the effect of inositol on those who, by virtue of a positive family history of diabetes mellitus, are at risk of developing gestational diabetes mellitus.

Previous hypothesis:
Inositol has been shown to have health benefits in those at risk of diabetes mellitus. We wish to investigate the effect of two different forms of inositol on those who, by virtue of a positive family history of diabetes mellitus, are at risk of developing gestational diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coombe Women and Infants University Hospital Research Ethics board, 18/09/2013, ref: 18/10 /13

Study design
Single-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Gestational diabetes mellitus

Interventions
Current interventions as of 09/04/2014:
Participants will be randomized to one of the following two groups:
1. Intervention group. This group will take D-chiro-inositol (11.8 mg) and folic acid (400 mcg) in combination
2. Control group. This group will take 400 mcg of folic acid

All of the above is dose per day. The duration of treatment is from recruitment at 10-14 weeks until delivery. They will be followed up until 6 weeks postnatally.

Previous interventions:
There are two intervention arms and one placebo:

1. Myoinositol 4 g + 400 mcg folic acid
2. 550mg myoinositol + 13.8 mg D-chiro-inositol + 400 mcg folic acid in soft gel caps
3. Placebo group: folic acid alone 400mcg

All of the above is dose per day. The duration of treatment is from recruitment at 10-14 weeks until delivery. They will be followed up until 6 weeks postnatally.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
D-chiro-inositol, folic acid

Primary outcome measure
Development of gestational diabetes mellitus, measured at 26 weeks gestation

Secondary outcome measures
1. Mode of delivery of the baby
2. Birth weight
3. Incidence of maternal or newborn morbidities

All of the above are recorded at delivery.

Overall study start date
01/11/2013

Completion date
01/02/2016

Eligibility

Key inclusion criteria
Any woman aged over 18 booking before 14 weeks with a first-degree relative who has diabetes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants

489

Key exclusion criteria
1. Multiple pregnancy
2. Known or suspected congenital abnormality
3. Any disease effecting the liver or pancreas

Date of first enrolment
18/11/2013

Date of final enrolment
10/07/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Coombe Women and Infant's University Hospital
Dublin
Ireland
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Sponsor information

Organisation
Coombe Women and Infant's University Hospital (Ireland)

Sponsor details
Cork Street
Dublin
Ireland
8

Sponsor type
Hospital/treatment centre

Website
http://www.coombe.ie/

ROR
https://ror.org/00bx71042

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Coombe Women and Infants University Hospital (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
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2017		Yes	No