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Preventing gestational diabetes with myo-inositol supplement

Submission date
03/01/2018

Recruitment status
No longer recruiting

Registration date
15/01/2018

Overall study status
Completed

Last Edited
14/03/2022

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
Gestational diabetes mellitus (GDM) is a condition with raised glucose (blood sugar) levels that is first diagnosed in pregnancy. It increases the risk of complications for mothers and their babies. There is a need for an effective, simple, acceptable and safe treatment to prevent gestational diabetes, which affects 1800 women every year in Barts Health Trust alone. To date, small studies have found that the over-the-counter nutritional supplement myo-inositol may reduce the risk of GDM. The uptake of this in mothers from inner city NHS trusts, which care for multi-ethnic, high-risk women, is not known. The aim of this small study (200 women) is to test the effectiveness of myo-inositol at preventing GDM before investing resources into a large-scale study (approx. £1.7 million).

Who can participate?
Women with a single pregnancy and at least one of the following risk factors: family history of diabetes, gestational diabetes in a previous pregnancy, obesity, minority ethnic family origin with a high prevalence of diabetes (such as South Asian, Middle Eastern and Black Caribbean), polycystic ovary syndrome, or previous macrosomic baby (birth weight over 4.5 kg)

What does the study involve?
Participants are randomly allocated to take a sachet of powder dissolved in water containing either myo-inositol or a placebo (dummy) supplement twice daily until delivery. Follow-up visits take place at 20, 28 and 34 weeks and delivery, aligning with the routine antenatal appointments. The study process is evaluated to examine the acceptability of the study and intervention to mothers, and identify reasons for non-participation and non-retention. The effects of myo-inositol on blood sugar are also estimated.

What are the possible benefits and risks of participating?
The results of this study will aid the development of further studies examining the effect of myo-inositol on the risk of GDM. Both supplements are vegan friendly. It is safe to continue any other nutritional supplements women may already be taking along with the study supplements. The potential for pain, discomfort, distress, inconvenience or changes to lifestyle as a result of participating in this study should be minimal. Taking the supplements might be a burden but research suggests that women are willing to take a daily nutritional supplement.

Where is the study run from?
1. Royal London Hospital (UK)
2. Newham University Hospital (UK)
3. Whipps Cross University Hospital (UK)
4. Manchester Royal Infirmary (UK)
5. St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2017 to April 2019

Who is funding the study?
1. Barts and the London Charity and Related Charities
2. NIHR CLAHRC North Thames
3. Pharmasure Ltd

Who is the main contact?
Dr Zoe Drymoussi

Contact information

Type(s)
Scientific

Contact name
Dr Zoe Drymoussi

Contact details
Yvonne Carter Building
58 Turner Street
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E1 2AB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35832

Study information

Scientific Title
Effectiveness and acceptability of myo-inositol nutritional supplement in the prevention of gestational diabetes: a pilot placebo-controlled double-blind randomised trial

Acronym
EMmY

Study objectives
Gestational diabetes, a condition with raised glucose levels that is first diagnosed in pregnancy, increases the risk of complications to mothers and their babies. There is a need for an effective, simple, acceptable and safe treatment to prevent gestational diabetes, which affects 1800 women every year in Barts Health Trust alone. Our systematic review identified the promising role of the nutritional supplement myo-inositol in reducing the risk of GDM. To date, small studies have identified the potential role of over-the-counter nutritional supplement myo-inositol in preventing gestational diabetes. The uptake of the intervention in mothers from inner city NHS trusts, which care for multi-ethnic, high-risk women is not known.

Prior to investing resources into a large-scale study (approx. £1.7 million) on testing the effectiveness of myo-inositol to reduce the incidence of GDM, we propose to undertake a smaller version (200 women) of the future large trial. The trialists propose to undertake a multi centre, randomised, placebo controlled, double blind pilot trial (EMmY), on myo-inositol supplementation in pregnancy to prevent GDM, to inform the large-scale definitive randomised trial. They will evaluate the study process, examine the acceptability of the study and intervention to mothers, and identify reasons for non-participation and non-retention. They will also obtain preliminary estimates of effects of myo-inositol on glycaemic parameters, and develop a core outcome set to be minimally reported in trials on prevention of GDM.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Queen Square Research Ethics Committee, 22/12/2017, ref: 17/EM/0394

Study design
Randomised; Interventional; Design type: Prevention, Dietary

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Specialty: Reproductive health and childbirth, Primary sub-specialty: Maternal/ Fetal medicine; UKCRC code/ Disease: Reproductive Health and Childbirth/ Other maternal disorders predominantly related to pregnancy, Metabolic and Endocrine/ Diabetes mellitus

Interventions
Randomisation will be done using an online system with a randomisation scheme based on permuted blocks of random block size (sizes 4, 6 and 8), stratified by participating site. No adaptive or minimisation strategies will be used in this trial.

The treatment arm will receive myo-inositol, and the control arm will receive a placebo. In both arms, the supplements are to be taken twice daily, from 12+0 to 15+6 weeks until delivery. After recruitment and randomisation, follow-up visits will be at 20 weeks, 28 weeks, 34 weeks, and delivery, aligning with the routine antenatal appointments.

Intervention Type
Supplement

Primary outcome measure
Process outcomes for the feasibility study:
1. Proportion of screened women who are eligible
2. Proportion of eligible women who are consented and randomised
3. Attrition rates at 28 weeks of pregnancy, and up to delivery
4. Adherence to treatment and to protocol
5. Deviations from the study protocol
6. Completeness of data collection
7. Determination of level of support required for the trial conduct
Timepoint(s): End of the study

Secondary outcome measures
Acceptability of the study and intervention assessed through qualitative research interviews and questionnaires, aimed at the participants, those who refuse consent to the study, and healthcare professionals involved in the study. Women who decline trial participation are offered an optional short open-ended questionnaire to capture any reasons. Interviews with participants will be carried out in a small proportion (approx. 10-20 women), at around 20 weeks and 34 weeks of pregnancy. Interviews with 10-15 healthcare professionals are carried out towards the end of the study.

Preliminary estimates of the effect of the intervention:
1. Clinical outcomes for mother and baby are collected from their medical notes at delivery
2. Laboratory outcomes of glucose metabolism tests, including an Oral Glucose Tolerance Test, are collected at the 28-week visit
3. Cost data including that of the intervention, lab tests, and clinic visits are assessed throughout the study
4. QALYs are assessed through the EQ-5D-5L questionnaire administered at baseline and delivery

Overall study start date
01/09/2017

Completion date
01/04/2019

Eligibility

Key inclusion criteria
1. Women with a singleton, viable pregnancy between 12+0 and 15+6 weeks gestation, based on ultrasound confirmation
2. Women with at least one of the following risk factors: family history of diabetes in any one of their first degree relatives, gestational diabetes in a previous pregnancy, obesity (BMI ≥30 Kg /m2), minority ethnic family origin with a high prevalence of diabetes (such as South Asian, Middle Eastern and Black Caribbean), polycystic ovary syndrome, or previous macrosomic baby (birth weight >4.5 kg)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Key exclusion criteria
1. Women known to have pre-existing type 1 or type 2 diabetes
2. Women considered to have undiagnosed type 2 diabetes, based on abnormal glycated haemoglobin (A1c) (HbA1c) levels and/or OGTT results before 15+6 weeks of pregnancy. Abnormal HbA1c levels defined as > = 48mmol/mol. Abnormal OGTT results defined as a fasting blood glucose level of > = 5.6mmol/l, or a 75g 2-hour blood glucose level of > = 7.8 mmol/l
3. Women using corticosteroids or metformin
4. Women who are not able to provide written informed consent in English

Date of first enrolment
01/02/2018

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal London Hospital
Whitechapel Road

London
United Kingdom
E1 1BB

Study participating centre
Newham University Hospital
Glen Road
Plaistow
London
United Kingdom
E13 8SL

Study participating centre
Whipps Cross University Hospital
Whipps Cross Road
Leytonstone
London
United Kingdom
E11 1NR

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE17 7EH

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Mile End Road
London
England
United Kingdom
E1 4NS

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Barts and the London Charity and Related Charities; Grant Codes: MGU0373

Funder Name
NIHR CLAHRC North Thames

Funder Name
Pharmasure Ltd

Results and Publications

Publication and dissemination plan
The study protocol is currently being prepared for publication. There are no plans at present to make available additional documents. The results from the trial will be submitted for publication in a major journal; it is anticipated that this will be within one year after the trial end date. The trialists will also disseminate their findings through their current social media links to provide lay and scientific bite-size summaries of the study results. They will disseminate the findings to local pregnancy support groups via members of Katie's Team (our patient and public involvement advisory group).

Intention to publish date
01/04/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/09/2018	29/10/2019	Yes	No
Results article		11/03/2022	14/03/2022	Yes	No