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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
London
United Kingdom
E1 2AB

# Additional identifiers

### Protocol serial number
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

## Primary study design
Interventional

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

## Study type(s)
Treatment

## 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(s)
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

### Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### 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
United Kingdom

England

### 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

**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

## 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? |
|---|---|---|---|---|---|
| Results article | | 11/03/2022 | 14/03/2022 | Yes | No |
| Protocol article | protocol | 24/09/2018 | 29/10/2019 | Yes | No |