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The study of myo-inositol supplements for reducing the risk of gestational diabetes mellitus

Submission date
03/05/2021

Recruitment status
No longer recruiting

Registration date
26/05/2021

Overall study status
Completed

Last Edited
02/03/2026

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 is high blood sugar (glucose) that develops during pregnancy and usually disappears after giving birth.
The purpose of this research study is to ascertain whether the chances of developing diabetes during pregnancy can be reduced through the use of a simple nutritional supplement in women who are pregnant.

Who can participate?
All pregnant women booked for prenatal care at Sidra Medicine will be approached regardless of age, language spoken and place for delivery

What does the study involve?
The study will involve monthly attendance at the antenatal clinic until delivery of the baby which will coincide with the regular antenatal visits. Each attendance will last for approximately 45 minutes to one hour and includes normal antenatal appointment with a Doctor or midwife. The first two appointments may be longer to allow a detailed explanation of the purpose of the study, how it will be conducted , obtain relevant consents and provide additional written information. A clinical dietician will call the participants after each visit to ask about lifestyle and dietary habits using short questionnaires.
The participants will be provided with the packet of the research supplements to be taken daily throughout the duration of the pregnancy. The supplement could either be Myoinositol or an inactive supplement, both of which are safe to use during pregnancy. The decision on which of the supplement will be received will be determined by chance, with every one having an equal chance of receiving either of the supplements. The researchers and yourself will not know which of these supplements you will receive to avoid unintended bias. Your standard antenatal care will consist of scheduled blood tests, ultrasound scan of the baby and antenatal consultations. The participants will be offered a test for diagnosing diabetes during pregnancy called the Oral Glucose Tolerance test(OGTT), between 6 and 7 months of pregnancy (24-28 weeks). This test is part of the standard antenatal care and will be offered even if the participant is not taking part in this research. The test usually takes about two hours to complete and involves three blood

samples, about table spoonful to be taken at hourly intervals. An additional blood sample, half a table spoonful (5 mls) will be taken specifically for the purpose of this research, this will measure the precursor of the Insulin hormone (C-peptide), to find out the reasons why some women develop diabetes in pregnancy and how to prevent it. All the visits related to this research will take place in the outpatient clinic setting, there will be no admission or overnight stay in the hospital related to this research.
The researchers will also collect details of the participants medical history, previous pregnancy history and the outcome of the current pregnancy from the hospital electronic medical records. The details of the baby including birth weight and condition at birth and mode of delivery will also be collected .

What are the possible benefits and risks of participating?
This study is for research purposes only. There could be potential benefits if it happens that you are randomized to the treatment arm, however neither you nor the Principal investigator knows which arm of the study you are randomized into until the end of the study.

The potential risks and side effects associated with procedures involved in the research are as follows:
Blood samples: possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
Taking the research supplements: There is no known risk we are aware of that is associated with taking the research supplement, which has been used widely around the world.

Where is the study run from?
Sidra Medical and Research Center (Qatar)

When is the study starting and how long is it expected to run for?
July 2019 to March 2024

Who is funding the study?
Sidra Medical and Research Center (Qatar)

Who is the main contact?
Dr Ibrahim Ibrahim, ibrahim2002@doctors.org.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
SDR200067

Study information

Scientific Title
Effect of antenatal dietary Myo-inositol supplementation in women during pregnancy on the incidence of gestational diabetes mellitus (GDM) and fetal outcome: A randomized controlled trial

Acronym
MiGDM

Study objectives
Myo-inositol supplementation in pregnancy reduces the risk of developing GDM

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2021, Sidra Medicine IRB (PO BOX 26999, Doha, Qatar; irb@sidra.org; +974 40036567), ref: 1538656

Study design
Prospective randomized double-blind placebo-controlled clinical trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of gestational diabetes in pregnant women

Interventions
Randomisation will be performed using computer generated numbers which would allocate participants into either Myo-inositol or Placebo arms. Both Myo-inositol and Placebo will have identical packaging prepared at source and supplied through Sidra pharmacy.
All research team members and research participants will be blinded to the content of the

research packs.
The Myo-inositol pack will contain 2 g of Myo-inositol whereas the placebo pack will contain a pharmacologically inert substrate, and both arms will have twice daily dosing.
Monthly (30 days) supply of the trial packs will be supplied and the research nurse will make scheduled contacts with all participants on a monthly basis, to arrange additional supply of trial packs and check on compliance.
These scheduled contacts will be linked to the regular antenatal clinic schedules, so that participants do not have to make extra visits. All participants will have standard antenatal care as per Sidra prenatal care pathway.
The Oral Glucose Tolerance test (OGTT) will be performed at 24-28 weeks as usual per Sidra protocol for routine screening for GDM. All participants will complete at least 12 weeks of intervention/supplementation prior to undertaking the OGTT.
Women will be advised to continue using the trial packs regardless of GTT results. Those who are diagnosed as having GDM will have standard antenatal care as per Sidra prenatal care pathway.
Participants will be advised to stop study supplements only when admitted in spontaneous labour, for Induction of Labour or Lower Segment Caesarean Section, whichever comes earlier.
The trial packs will be sourced from a supplier with previous expertise in preparation and packaging of RCT pharmaceutical samples, specifically Myo-inositol and identical placebo. The rest of the material resource required are currently available within the Antenatal service framework at Sidra, including the clinical and laboratory service for the standard Oral Glucose Tolerance Test.
Women will be given contact number to report any adverse effects which will be documented and communicated to the research team.
Data regarding pregnancy course and delivery outcome will be collected by the research nurse.
Recruitment will continue for 18 months and closing window of 6 months will be used.
Final un-blinding of the study data will occur at the completion of the trial, after the delivery of the participant who was recruited last. Un-blinding will also occur in the event of any adverse reaction to the study supplement.
Recruitment will continue for 18 months with a closing window of 6 months.

• The duration of study participation in this study will last between 24 weeks to 32 weeks (depending on the time of randomization, usually before 16 weeks of gestation)
• We also expect that this research study will last approximately two years to complete recruitment although each participant involvement will only be until the end of their pregnancy
• These scheduled contacts will be linked to their regular antenatal clinic schedules, so that participants do not have to make extra visits
• All participants will have standard antenatal care as per Sidra prenatal care pathway
• The Oral Glucose Tolerance test (OGTT) will be performed at 24-28 weeks as usual per Sidra protocol for routine screening for GDM
• All participants will complete at least 12 weeks of intervention or supplementation prior to undertaking the OGTT
• Women will be advised to continue using the trial packs regardless of GTT results
• Those who are diagnosed as having GDM will have standard antenatal care as per Sidra prenatal care pathway for women diagnosed with GDM

Intervention Type
Supplement

Primary outcome(s)
The occurrence of GDM measured using Oral Glucose Tolerance Test at 24 - 28 weeks of gestation

Key secondary outcome(s))
1. Maternal:
1.1. Gestational weight gain measured using antenatal maternal records from the first recorded maternal weight and the final maternal weight
1.2. Need for metformin or insulin therapy measured using antenatal maternal records throughout pregnancy
1.3. Mode of delivery measured using maternal records at the time of delivery
1.4. Hypertension in pregnancy measured using maternal records

2. Fetal:
2.1. Large for Gestational Age at delivery (weight >95th centile for gestation) measured using fetal weight as centile at delivery
2.2. Small for Gestational Age at delivery (weight <10th centile for gestation) measured using fetal weight as centile at delivery
2.3. Macrosomia (fetal weight ≥4000 g at delivery) measured using actual baby weight as centile at delivery
2.4. Shoulder dystocia and birth injury measured using maternal records at time of delivery
2.5. Polyhydramnios measured using maternal records from the latest ultrasound report before delivery
2.6. NICU Admission for >24 h measured using infant records after delivery
2.7. Neonatal hypoglycaemia requiring intravenous glucose measured using infant records after delivery
2.8. Preterm delivery (<37 weeks gestation) measured using maternal records at time of delivery
2.9. Transient tachypnea of the newborn measured using infant records after delivery
2.10. Respiratory distress syndrome measured using infant records after delivery

Completion date
01/03/2024

Eligibility

Key inclusion criteria
1. All pregnant women booked for prenatal care at Sidra Medicine will be approached regardless of age, language spoken or place for delivery
2. Gestational age less than 16 weeks
3. Capacity to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment

67

Key exclusion criteria
1. Pre-gestational diabetes
2. Booking fasting glucose of ≥5.1 mmol/l (92 mg/dl)
3. Women on steroids during pregnancy
4. Women using metformin for any other disorder e.g. PCOS
5. Women taking Myo-inositol as part of any supplementation
6. Cancer not in remission
7. Women who lack the capacity to provide informed consent
8. Women who had bariatric surgery
9. Involvement in another interventional trial
10. Polyhydramnios (this is a very unlikely finding before 16 weeks)

Date of first enrolment
15/10/2021

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
Qatar

Study participating centre
Sidra Medicine
Alqta street
Doha
Qatar
PO BOX 26999

Sponsor information

Organisation
Sidra Medical and Research Center

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sidra Medical and Research Center

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/02/2026	02/03/2026	Yes	No
Protocol article		04/01/2022	10/06/2025	Yes	No
Other publications		24/09/2025	10/10/2025	Yes	No