IRB-400 Informed Consent Form For Research Study

Protocol Title:	**Effect of antenatal dietary Myo-inositol supplementatiom in women during pregnancy on the incidence of gestational diabetes mellitus and fetal outcome : A randomized controlled trial (MiGDM TRIAL)**
Protocol Number:	**1538656**
Sponsor:	**Sidra Medicine-IRF**
Principal Investigator:	**Dr Ibrahim Mamoun Ibrahim**
Site Address:	**Sidra Medicine, Doha, Qatar**
Telephone Number:	**30016566**

1. Introduction

Before agreeing to participate in this research study, please read and understand the following explanation of the proposed study. This informed consent form describes the purpose, procedures and risks of the study. It also describes your right to withdraw from the study at any time, and that you are volunteering. Also, that no guarantees or assurances can be made as to the results of the study. Please feel free to ask questions.

2. Background and Purpose

The background and purpose of this research study is to ascertain whether we can reduce the chances of developing diabetes during pregnancy through the use of simple nutritional supplement in women who are pregnant.

Diabetes is a relatively common health problem in Qatar and during pregnancy up to one in four pregnant women are affected by diabetes in Qatar. Pregnancies affected by diabetes carry additional problems for the expectant mother and her unborn baby. Some of these problems can be prevented or reduced through the use of currently available treatments. Treatments currently used for diabetes during pregnancy include targeted dietary and lifestyle changes as well as the use of tablets or injection (insulin) to keep blood sugar level within a healthy range. Whilst these treatments are helpful , they can be time-consuming , inconvenient and carry potential side-effects particularly treatment by injection. In addition, the problems caused by diabetes to the mother and her unborn baby are not always preventable even when current treatments are used. Therefore, the ideal goal if possible, is the to prevent diabetes during pregnancy altogether, and this is the reason we are undertaking this research study. By reducing the chances of developing diabetes during pregnancy, problems associated with having diabetes can also be reduced or prevented altogether.

3. Number of Subjects

About 640 subjects will participate in this study and this is the only site for the entire study nationally.

4. Study Duration and Length of Participation

Your participation in this study will last approximately 32 weeks and will include a maximum of 8 visits to the study center. We also expect that this research study will last approximately two years to complete althoughyour involvement will only be till the end of your pregnancy.

5. Procedures

Your participation will involve attendance at the Sidra Obstetric clinic which is located on the fourth floor of the Sidra outpatient building. There will be monthly attendances from the time you enroll to participate in the study until delivery of the baby and this will coincide with your regular antenatal visits. Each attendance will last for approximately 45 minutes to one hour and includes your normal antenatal appointment with a Doctor or midwife. The first two appointments may be longer to allow a detailed explanantion of the purpose of this research and seek your written permission. The reseach coordinator will meet with you at your first visit and provide a detailed explanation of the research and also provide you with a direct contact telephone number and additional written information about the research in addition to arranging the follow up visit. A clinical dietician will call you after each visit to ask about your lifestyle and dietary habits using short questionnaries.

Your participation will involve the collection of a packet of research supplements to be taken daily throughout the duration of your involvement in the research. The supplement could either be myoinositol or an inactive supplement, both of which are safe to use during pregnancy.

You 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 you were 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 resons 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.

If you agree to participate, the researchers will also collect details of your medical history, previous pregnancy history and the outcome of your 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 .You will have your standard antenatal care whether or not you choose to participate in the research. Your standard antenatal care will consist of scheduled blood tests, ultrasound scan of the baby and antenatal consultations. If you choose to take part in the research, you will be required to take the research supplement on a daily basis. The research supplement contains either Myoinositol or an inactive supplement. The researchers and yourself will not know which of these supplements you will receive to avoid unitended bias. The decision on which of the supplement you will receive will be determined by chance, with every one having an equal chance of receiving the Myoinositol or the inactive supplement.

6. Alternative Procedures

This study is for research purposes only. The only alternative is to not participate in this study and you will have your standard anatenatal care as usual

Ibrahim I, *et al. BMJ Open* 2022; 12:e055314. doi: 10.1136/bmjopen-2021-055314

7. Risks, Side Effects and/or Discomforts

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 , having been used widely around the world.

8. Unforeseen Risks

There are no known risk for study participation . The safety to the fetus is not studied well, but there is no known or foreseeable risk to the fetus from myo-inositol or placebo.

9. Pregnancy *(include if applicable)*

This research is designed specifically for participants who are currently pregnant.

10. New Findings

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you. This might include changes in procedures, changes in the risks or benefits of participation, or any new alternatives to participation that the researchers learn about.

11. Individual Results from the Research Tests/Surveys

Generally, tests done for research purposes are not meant to provide results or clinical information that apply to you alone

12. Benefits

This study is for research purposes only. There could be potential benefits if it happens that you are assigned to one of the 2 treatment arms (Myoinositol or placebo), however neither you nor the Principal investigator knows which arm of the study you are assigned into until the end of the study.

A brief fact sheet about Myoinositol is provided along with this consent form for information only.

13. Costs

There will be no charge to you for your participation in this study. The study-related procedures will be provided at no charge to you or your insurance company. The study visits will be aligned with your standard antenatal care visits according to the agreed care plan with Sidra Medicine.The cost of the routine visit will be according to the agreed care plan with Sidra Medicine and will not be paid by the research funds.

14. Compensation for Participation

You will not receive any monetary compensation for your participation in this study.

15. Research Related Injuries

If you are injured or made sick from taking part in this research study, call Dr Ibrahim Ibrahim immediately, T. +974-30016566, or alternatively contact Sidra Medicine Emergency Department.

Medical care will be provided to you at Sidra Medicine at no charge. In case we were unable to provide care to you at Sidra, we will arrange and pay for your care at Hamad Medial Corporation (HMC). If you receive care at another institution, you or your insurance will have to pay for that care in accordance with the

policies of that institution. Sidra Medicine has no program or funds set aside to compensate you for research-related injuries or to pay for medical care for research-related injuries at institutions other than HMC or Sidra. Contact the Principal Investigator for more information

16. Confidentiality

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document. Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information.

The investigator, authorized research personnel, the sponsor or persons working on behalf of the sponsor, monitors, auditors, MOPH, other regulatory agencies (when applicable) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. They will be granted direct access to your medical records for verification of the research procedures and date. Therefore, absolute confidentiality cannot be guaranteed. By signing this document, you are authorizing this access.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We will take careful steps to keep your information confidential.We will store your identifiable information, in a password-protected database; encrypted file which changes it to another format to protect it from being accessed by anyone outside of the approved staff.

We will remove your name or other direct identifiers from your information or samples. We will label your information or samples with a code. We will store the key that links the code to your identity separately. Only select staff will have access to the list that links the code to you.

The staff follow procedures to keep your identity secret to the extent allowed by law. In very unusual cases, staff may be required to release your identifiable medical and research information to the extent allowed by law.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

17. Commercial Gain

Your information or samples collected during this study will no longer belong to you. Information or samples may be used for the development of new products, treatments, processes or services for commercial sale. There are no plans to offer you financial compensation or share any profits with you or your relatives should this occur.
You will not, however, lose any legal rights to which you are entitled by signing this consent.

18. Research Team Contact

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, contact the investigator Dr Ibrahim Ibrahim on +974 30016566

19. IRB Contact

An Institutional Review Board (IRB) is an independent committee established to help protect the rights of research subjects. IRB at Sidra has reviewed and approved this study. Both the IRB at Sidra and the Qatari Ministry of public helath(MOPH) will be promptly notified in the event of research related injury. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, Email: irb@sidra.org, or T. +974-4003-7747 during business hours Sunday- Thursday 7:30 a.m. to 4:00 p.m.

20. Voluntary Participation/Withdrawal

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

If you choose to withdraw from the study after a period of participation, you will continue to receive your pregnancy care according to the standard schedule of antenatal, intrapartum and postpartum care. You will be asked to return the unused trial packs to the research nurse to complete the appropriate documentation.The research nurse will return the unused packs to the trial Pharmacist.

The investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is cancelled.

21. Place and Duration of Storage of Information or Samples

The information will be stored at Sidra Medicine, Doha, Qatar for no longer than 3 years. Only the Investigator or authorized Sidra research team members will have access to the information.

22. Providing Information or Samples to Recipient Researchers (include if applicable)

Before sharing your information we will replace identifiers such as (e.g., your name, medical record number, or date of birth) with a code. Your coded information may be shared with other Sidra researchers and researchers outside of Sidra, without your additional informed consent.

23. Optional Future Use:

Do you give permission for Dr Ibrahim Ibrahim under the auspices of Sidra Medicine to store and share your information for future research in compliance with applicable regulations and institutional policies?

☐ **Yes** ☐**No** Initials

Remember, you can still be in the main study even if you even if you do not wish to allow your information and/or specimens stored for this investigator's future research.

24. Participating in Future Studies

The research staff would like to contact you with information about participating in future studies.
You give your permission for the investigator or staff to contact you regarding your willingness to participate in future research studies? ☐ **Yes** ☐**No** Initials

25. Consent

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions. All my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

26. Consent for Subjects Who Cannot Read *(include if applicable)*

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness* Date

**Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance*

27. For Children Who Become Adults *(include if applicable)*

Not applicable