Mater Research

Participant information and consent form — Trial details

The MODY in GDM project

An invitation from

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1 Would you like to take part in this clinical trial?

We would like to invite you to take part in our clinical trial. This is because you have been diagnosed with Gestational Diabetes Mellitus (GDM) by a glucose tolerance test and referred to the Nutrition and Dietetics Clinic at the Mater Mothers' Hospital for treatment.

This document tells you about the trial and describes what will happen if you decide to take part. If there is anything you don't understand or want to know more about, please ask us.

You might also want to talk to a relative, a friend or your GP before you make up your mind. If you decide to go ahead, we will ask you to sign the consent form (the last page of this document). We will give you a copy of the complete signed document to keep.

2 Why are we doing this research?

The purpose of this research is to see whether all women diagnosed with gestational diabetes should be offered testing for a genetic form of diabetes called Maturity-Onset Diabetes of the Young (MODY).

A small proportion, no one really knows how many, of women diagnosed with GDM have a genetic (inherited) form of diabetes called MODY. The importance of knowing whether a woman has MODY is that it may affect the growth of the unborn baby during pregnancy unless specific treatment is given. It is also useful to know if a person has MODY because in the long term, after pregnancy, it is often wrongly diagnosed and treated as the commoner Type 2 or Type 1 diabetes while in most cases, it could be treated more simply and may carry a lower risk of diabetic complications.

The MODY in GDM project offers genetic testing for MODY to women who have been diagnosed with GDM from a glucose tolerance test. The test analyses 13 genes that have been shown to cause MODY. If MODY is diagnosed a woman will be advised to have treatment for MODY in pregnancy at the Obstetric Medicine Clinic of the Mater Mothers' Hospital. If MODY is not diagnosed the woman will be advised to continue her routine treatment for GDM at the Mater Mothers' Hospital.

As mentioned above, the aim of the study is to determine whether MODY testing should be offered to all women diagnosed with GDM. This will depend on whether MODY testing, and treatment of affected women, can be shown to improve pregnancy outcomes for mothers and their babies, for example, by preventing complications that may have led to treatment of the baby in a special care nursery. To investigate this, we would like to test 480 women with GDM who will then be treated for either MODY or GDM depending on the results. If you agree to be tested, the details of your treatment, the birth of the baby and your general wellbeing will be collected through routine clinic visits and by completing 2 or 3 short questionnaires. You will be asked to complete the questionnaires when you have the blood test for MODY, at around 36 weeks of pregnancy and then about 6 weeks after the birth. Using all this information we will be able to understand how many women diagnosed with GDM really have MODY, whether MODY testing in GDM is good for mothers and babies and whether it is cost-effective to offer MODY testing to all women with GDM.

3 Do I have to take part?

No. It's your choice. If you don't wish to take part, you don't have to and you do not have to give a reason. If you decide to take part and later change your mind, you are free to withdraw at any stage and you do not have to give a reason. If you choose not to take part, or if you choose to take part and then later withdraw, you will still be able to access your usual medical care. Your choice will not affect your relations with those treating you, or with this institution.

If you do withdraw your consent during the clinical trial, the research team will stop collecting personal information from you. But they will keep the personal information they have collected up to that point. There is a good reason for this. Sometimes, the law requires it. It is also retained for accurate measurement, the trial results must include all the data actually collected.

Just to be clear on this point. We must keep any information about you we collect, up to the time you withdraw. If you do not agree with this then we cannot allow you to join the clinical trial.

4 What are the main steps in the study?

1. If you agree to take part in the study, you would sign the consent form and have blood collected by the Mater Research Nurse or Mater Pathology blood collector for MODY gene testing.
2. There are 2 short questionnaires about your general wellbeing which can be completed on paper when you sign the consent form or online (we will give you the link).
3. MODY testing will take up to 3 weeks. If MODY is diagnosed, you will be contacted by telephone by a doctor from the Obstetric Medicine Clinic from Mater Mothers' Hospital to discuss the result and arrange an appointment at the clinic. MODY in pregnancy is typically monitored with regular ultrasounds to make sure that the baby is growing normally. Medication may not be required. If MODY is diagnosed, you will be referred to a genetic counsellor at Genetic Health Queensland to discuss the diagnosis and given a letter to pass on to immediate family members (blood-relatives) to recommend that they get tested.

   If MODY is not diagnosed you will not be contacted by telephone but will be advised of the result at your next routine visit to the Nutrition and Dietetics Clinic at Mater Mothers' Hospital for treatment of your GDM.

4. At around 36 weeks of pregnancy we will email to ask you to complete the same 2 questionnaires that you completed at the beginning and another short list of questions, for instance about extra GP visits or out-of-pocket expenses you have had relating to the treatment of MODY or GDM throughout your pregnancy. One questionnaire will ask about your income to help identify any inequality between income and health.
5. Finally, about 6 weeks after delivery, we will email to ask you to complete the same 3 questionnaires that you kindly completed just before the baby was born.

We first need to confirm that you are eligible to take part.

Women who have been diagnosed with gestational diabetes mellitus (GDM) by an oral glucose tolerance test will be invited to take part unless they have had a normal glucose tolerance test in the current pregnancy. If MODY is diagnosed you will be offered a letter to give to your close blood-relatives to suggest that they speak to their doctor and be tested for MODY. This testing and genetic counselling are available through Genetic Health Queensland. If you believe that you would not be happy to give this letter to your blood-relatives we cannot allow you to join the clinical trial. Also, if you are aged less than 18 years and are not able to get consent from your legal guardian, we are not able to test you for MODY.

5 What other options do I have?

You do not have to take part in this trial to receive the right treatment for your GDM. At the moment, MODY testing is only requested under very specific circumstances as we are really not sure who should be tested and it is not funded by Medicare. This is why we are doing this study. However, if you do not wish to take part in the study but would like MODY testing, your doctor can request it. As the test is not funded by Medicare it will cost you $1100.

6 Who is conducting and paying for this research?

The project is funded by a Queensland Genomics Health Alliance (www.qgha.org) grant. The Mater Research Clinical Research Coordinator will regularly assess the trial, ensuring that the research protocol is adhered to, the data collection and storage is accurate and secure, and that any problems are reported appropriately.

7 What will happen to information about me?

We will keep any information confidential and securely stored. We will use and retain information that we collect about you only for this clinical trial. We will not disclose your information without your permission, except in compliance with the law.

Information about you may be obtained from your health records held at this institution. If you sign the consent form, you agree to the study team accessing health records if they are relevant to your participation in this study.

All of the collected data will be coded. No personal information about you, such as your name and address will leave the clinic, and in all study information sent out from the clinic you will be identified with a code number only. All of your collected information related to the study will be kept for at least 15 years after the end of the study. After the 15 years this information will be permanently deleted from the computer system and any hard copies will be destroyed. However, your official Mater medical records will be kept for the length of time required by government health regulations, which in the case of genetic (MODY) testing is 100 years.

Australian and Queensland privacy laws give you the right to request access to your information that the researchers have collected and stored. The law also gives you the right to request corrections to any

information about you that you disagree with. Please contact the study team (contacts on pages 4 and 5 of this document) if you would like to access your information.

8 What are my responsibilities during the trial?

If you agree to participate in this study you agree to have the test for MODY and complete the questionnaires at the time of enrolment in the trial, just before birth and 6 weeks after the birth. If you cannot, or do not wish to accept this responsibility, then we cannot accept you as a participant in the trial.

9 What possible benefits might I get by taking part?

The possible benefits of taking part would apply to women who have MODY rather than GDM. They are:

1. Having your diabetes correctly identified as MODY rather than GDM would allow treatment specific for MODY during pregnancy, which would be better for you and, in some cases, safer for the baby.

2. Receiving the correct treatment for diabetes in the long term. Most cases of MODY require either no treatment or low dose oral medication. MODY is a lifelong condition and is usually incorrectly diagnosed and treated as Type 2 or Type 1 diabetes. Knowing that the diagnosis is MODY would prevent this incorrect treatment.

10 What risks do I run by taking part?

The risks of participation include possible bruising at the blood collection site, feeling faint during blood collection and skin infection at the site of blood collection. The blood sample will be taken by staff who are trained and experienced in phlebotomy.

There also a risk that you may feel distressed if MODY is diagnosed. The distress may arise from knowing that, because MODY is a genetic condition, there is a 50% likelihood of it being inherited by the next generation. Also, some MODY types are associated with abnormalities of the kidneys or urinary tract, reproductive system or other organs and, if these are found, your distress may increase. Family members who are tested and diagnosed with MODY may also experience distress for the same reasons. You, and they, will be offered counselling by a genetic counsellor at Genetic Health Queensland to discuss the implications for you of having MODY. However, this is an important diagnosis to make as it will allow appropriate treatment for MODY during pregnancy and afterwards. Also, family members will benefit from being screened, if they wish, and appropriately treated. A diagnosis of MODY may affect applications for life or income protection insurance. Most MODY diagnoses are associated with lower risk of complications than Type 2 or Type 1 diabetes so in most, but not necessarily all, cases the genetic diagnosis is likely to favour the applicant.

11 How will you use any tissues or samples you take from me?

If you agree to participate in this trial, we will take 10 mL (the size of a dessertspoon) of blood to use for the MODY test. As the MODY is test a routine test performed by Mater Pathology your sample will be processed in the same way as all pathology specimens for this type of testing. For participants who are not found to have MODY the sample will be stored for 3 months after the results are reported, as per national requirements for this type of testing. After storage, samples are discarded by incineration. The samples of participants who do have MODY will be stored indefinitely because they are used to confirm results if the participant's relatives request the same testing.

Results will be stored in your confidential personal health records at Mater in the same way that all pathology results are stored.

Will you be doing any genetic tests?

Yes. The test for MODY involves analysing genes which, if abnormal, have been shown to cause MODY. There are 13 genes that have been shown to cause MODY if an abnormality (mutation) is present. Each of these genes will be tested in this trial. As only the 13 known MODY genes will be tested there is no chance that information about any other health condition or parental relationship can be identified.

If MODY is diagnosed you will be offered a letter to give to your close blood-relatives to suggest that they speak to their doctor and be tested for MODY. This testing and genetic counselling are available through Genetic Health Queensland. If you believe that you would not be happy to give this letter to your blood-relatives we cannot allow you to join the clinical trial.

If you withdraw from the study you can request that your samples be destroyed.

12 What happens if I am injured as a result of my participation in this trial?

If, as a result of your participation in this study, you are injured, immediately advise your study doctor of your condition. In the first instance your study doctor will evaluate your condition and then discuss treatment with both you and your regular treating doctor.

Since you are participating in a non-sponsored study/investigation any question about compensation must initially be directed to your study doctor who should advise their insurer of the matter.

13 Will you pay me to participate in this trial?

There is no reimbursement or payment for this trial.

14 Will the results of the trial be published?

To protect your privacy, no information will be published that could identify you as a participant in this trial. When the trial is complete we intend to publish Queensland Clinical Guidelines for MODY testing in pregnancy to guide clinicians in their approach to diagnosing MODY in women who have gestational diabetes.

15 What if I have a question or need to make a complaint or seek compensation for injury?

We have included several contacts for you below. Who you contact depends on what information you need.

For all study enquiries or if you want to talk to the study team:

- A business-hours contact for the study team.
  Dr Janet Warner, Director of Chemical Pathology
  (07) 3163 6352
  janet.warner@mater.org.au

If you wish to discuss the study or with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact:

- Reviewing Human Research Ethics Committee
  Mater Misericordiae Ltd Human Research Ethics Committee

(07) 3163 1585
research.ethics@mmri.mater.org.au

- A contact at the research site to whom patients may take complaints or requests for compensation.
  Mater Hospital Patient Representative
  (07) 31638303
  roxanne.regan@mater.org.au

16 The consent form

Sign the consent form only after you have made up your mind to take part in this clinical trial. All study participants must be provided with a signed and dated copy of the participant information and consent form for their personal record.

Consent form

Title	Evaluation of Clinical, Ethical and Economic Factors in Targeted Genetic Testing for Maturity-Onset Diabetes of the Young in Gestational Diabetes	
Short title	The MODY in GDM project	
Protocol number	[Protocol number]	
Project sponsor	Mater Misericordiae Ltd	
Principal investigator	Professor John Prins	
Clinical contact person	Dr Janet Warner	07 3163 6352 janet.warner@mater.org.au

Note: All parties signing the consent section must date their own signature.

Declaration by participant

I have read, or have had read to me, and I understand the participant information and consent form.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this clinical trial as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand the purposes, procedures and risks of the research described in the trial.

I consent to my treating doctor/s being notified of my participation in this study and any clinically relevant information noted by the trial doctor in the conduct of the trial.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature of Participant _____

Date _____/_____/_____

Name of parent/legal guardian (if under 18) (please print)

_____

Signature of parent/legal guardian _____

Date _____/_____/_____

Declaration by trial doctor/senior researcher†

I have given a verbal explanation of the clinical trial, its procedures and risks and I believe that the participant has understood that explanation.

Signature _____ Date_____

Name of trial doctor/ researcher† (please print) _____

† A senior member of the research team must provide the explanation of, and information concerning, the clinical trial.