

GEMS



INFORMATION FOR PREGNANT WOMEN

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BACKGROUND

You are invited to take part in GEMS, a study that is assessing how to best detect diabetes (gestational diabetes mellitus or GDM) in pregnant women.

For over 25 years, pregnant women with specific blood sugar concentrations have been diagnosed with GDM and offered treatment. Recently, it has been suggested that GDM should be diagnosed at lower blood sugar concentrations. With the lower criteria, some additional women will be diagnosed with GDM, although it will likely be mild.

WHY ARE WE DOING THIS STUDY?

High blood sugar which starts during pregnancy is known as GDM. If a mother has GDM, this can cause health problems for her and her baby during pregnancy and birth. Babies born to mothers with GDM may be large-for-gestational age (LGA), suffer birth injuries, breathing problems, jaundice and low blood sugar which, in severe cases, can cause brain injury. Long-term health risks to the

mother include an increased risk of developing Type 2 diabetes and heart disease. Babies born to mothers with GDM have an increased risk of growing up overweight or obese and of developing diabetes in adulthood. In New Zealand, the Ministry of Health recommends that all pregnant women are tested for GDM and offers the choice of participation in studies such as GEMS.

It is very important that we find out which blood sugar concentrations are the most appropriate for diagnosing GDM to try to reduce the health problems it can cause.

WHAT DOES THE STUDY INVOLVE?

If you choose to participate in GEMS and give your written consent, you will be randomly assigned to one of two study groups – one which uses the current threshold to test for GDM, and the other which uses the lower threshold. You will be tested for GDM by having an Oral Glucose Tolerance Test arranged by your midwife. You will be asked to complete a questionnaire about your diet and

exercise patterns and your health and well-being and may have a blood sample and body measurements taken when you enter the study, at 36 weeks' pregnant, and when your baby is six months old. After birth, a blood sample from your baby's umbilical cord and body measurements may also be collected.

WHAT IF I AM DIAGNOSED WITH GDM?

Most women in GEMS will not have GDM. If your blood sugar results show you have GDM you will receive standard care for this from your midwife. This may include attending the Diabetes in Pregnancy Service and receiving dietary advice, blood sugar monitoring, and medications if needed.

AM I ELIGIBLE FOR THE GEMS STUDY?

To be eligible for GEMS you must:

- Be between 24 and 32 weeks pregnant with one baby
- Have no history of GDM or diabetes mellitus (Type 1 or 2)
- Give informed consent

WHO CAN I CONTACT FOR MORE INFORMATION?

Please check out the GEMS website: www.ligginsinstitute.org/GEMS

If you would like to talk to someone about GEMS, please call 09-923-1356 and one of our research midwives will be in touch with you.

Alternatively, you can email us at gems@auckland.ac.nz



GEMS is being conducted by the Liggins Institute at the University of Auckland. The Chief Investigator is Professor Caroline Crowther.

This study has received ethics approval from the Health and Disability Ethics Committee (HDEC) and from the Auckland District Health Board Research Committee.

HDEC Reference: 13/NTB/18/AM01

MY RIGHTS

If you have any questions about your rights as a participant in this study, you can contact an independent health and disability advocate via the Health and Disability Commissioner Act:

Telephone: 0800 555 050

Email: advocacy@hdc.org.nz

THANK YOU FOR YOUR INTEREST!

Your LMC can help you to join the GEMS Study.