



## Continuous Glucose Monitoring in Women with Type 1 Diabetes in Pregnancy Trial (CONCEPTT)

### Objective:

The primary objective of the study is to determine if real-time continuous glucose monitoring (RT-CGM) can improve glycemic control in women with type 1 diabetes (T1D) who are pregnant or planning pregnancy.

### Study Design:

This is the first global trial of CGM in pregnancy. This study will consist of two parallel trials that are multi-centred, randomized, open label, and controlled with an intention-to-treat analysis. Women with T1D in pregnancy who are less than 12 weeks and six days gestation, as well as women planning pregnancy, who pass the run-in period, will be eligible. The run-in period will be a six day period during which time women will wear the RT-CGM to ensure that they can understand the device and that they will be compliant with its use. Eligible women will be randomized to receive RT-CGM along with their standard intensive insulin regimen, or continue on their standard intensive insulin regimen without RT-CGM. Randomization will stratify for type of treatment (pump or multiple dose injections (MDI)), and baseline HbA1c (for pregnant women: less than 7.5, or greater or equal to 7.5; for women planning pregnancy baseline, less than 8.0, or greater or equal to 8.0).

### Reason for Study:

Poor glucose control during pregnancy results in a number of serious complications for both mother and infant. Preeclampsia (high blood pressure and protein in the urine after the 20<sup>th</sup> week of pregnancy) and preterm birth are much more common in women with T1D, and over 60 per cent of children are born with macrosomia (above the 90<sup>th</sup> percentile by birth weight). In addition to maternal complications, these infants are at higher risk of developing type 2 diabetes and adult chronic illness later in life. This international study, led by Canadian investigators, will test: 1) whether CGM use during pregnancy can improve glucose control and reduce the incidence of macrosomia and infant difficulties; and 2) whether CGM use in women planning pregnancy will improve glucose control to facilitate pregnancy and improved outcomes. It has been designed as the definitive trial on the subject and is likely to form the basis for changes in standards of obstetric care for women with T1D worldwide.

### Study Contacts:

If you are interested in participating in CONCEPTT, please contact the study coordinator at the clinical site nearest to you to learn more about how to enrol.

Principal Investigator: Denice Feig, MD (Mount Sinai Hospital, Toronto)

Locations: Toronto, Hamilton, Ottawa, London, and Kingston

### Trial Coordination Centre: The Centre for Mother, Infant, and Child Research (CMICR), Sunnybrook Research Centre

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**Additional Sites – Coming Soon:**

**Toronto – Women's College Hospital**

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**Toronto – St. Michael's Hospital**

Site Investigator: Maria Wolfs, MD

**Hamilton – McMaster University**

Site Investigator: John Booth, MD

**Ottawa – The Ottawa Hospital, Riverside Campus**

Site Investigator: Erin Keely, MD