closed-loop insulin delivery in pregnant women with type 1 diabetes: a randomized controlled trial

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this research answers the need to evaluate whether the 780G hybrid closed-loop system in pregnant women with T1DM can improve glycaemic control with less hypoglycaemia. This in turn, might improve pregnancy outcomes in women with T1DM.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON49884

Source
ToetsingOnline

Brief title
CRISTAL study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Pregnancy, labour, delivery and postpartum conditions

Synonym
diabetes, diabetes mellitus type 1

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Ziekenhuis Leuven
Source(s) of monetary or material Support: DiabetesLiga bij de Koning

Boudewijnstichting;Medtronic BV,Medtronic B.V.

Intervention

Keyword: hybrid closed loop insulin delivery, pregnancy, type 1 diabetes mellitus

Outcome measures

Primary outcome

time in range (glucose 3.5-7.8 mmol/l)

Secondary outcome

* Number and duration of hypoglycaemic episodes (time glucose <3.5 mmol/l, time <2.8 mmol/l).

* Glucose variability, mean glucose level and percentages of time in target overnight, during the day and evening.

* Total insulin dose.

* Continuous glucose monitoring compliance.

* Treatment satisfaction.

* Pregnancy outcomes.

* The cost-effectiveness of the closed-loop system compared to standard of care.

Study description

Background summary

Type 1 diabetes during pregnancy leads to a higher risk of several complications for mother as well as the child (such as preterm birth, caesarian section, pre-eclampsia). The most important goal of the antenatal care is to obtain well regulated glucose levels, because that is associated with better pregnancy outcomes. However, strict glucose regulation during pregnancy is difficult to obtain. The purpose of the current study is to assess whether a

closed loop systen combined with a glucose sensor (the 780G MiniMed insulinpump, Medtronic bv) leads to better glucose control without increase of hypoglycemic events in pregnant women with type 1 diabetes. Earlier research showed that use of continuous glucose monitoring leads to better pregnancy outcomes, but whether a closed loop system further improves outcomes is not known. This closed loop system was given a CE-mark in Europe from May 2020 for the use in patients with diabetes mellitus type 1. It's use in pregnant women has not been approved yet.

Study objective

this research answers the need to evaluate whether the 780G hybrid closed-loop system in pregnant women with T1DM can improve glycaemic control with less hypoglycaemia. This in turn, might improve pregnancy outcomes in women with T1DM.

Study design

randomised, open-label, study

Intervention

intervention arm: treatment with the 780G MiniMed insulin pump combined with continuous glucose monitoring
control arm: standard care

Study burden and risks

- at a maximum of 6 moments in pregnancy, extra blood will be taken for the purpose of the study (maximum 24ml per drawing) and will be asked to fill in questionnaires. Filling in the questionnaires will take 20-30 minutes and will be plannend during a regular visit at the diabetes clinic. (Participants do not have to come to the hospital only for study purpose.)
- participants in the intervention arm change their diabetes treatment. Before starting the intervention treatment, they will be educated which will take approximately 4 hours. As can occur with the use of any insulin pump, technical problems are possible that can lead to malfunction of the insulin supply from the 780 pump (such as when the catheter is blocked). This can rarely lead to diabetic keto-acidosis (DKA). The 780G system has built-in safety systems that alert to such problems and indicate how the problem can be solved. It will always be ensured that an alternative emergency treatment with insulin injections is available in the rare case that the technical problems cannot be solved immediately. Also the technical helpdesk of the manufacturer will be available 24/7.
- The participants in the control arm will be asked to wear a blinded glucose monitor during 21 days for a maximum of 5 times during pregnancy. This is

necessary to be able to evaluate the glucose levels between the intervention and control arm in a standardized way. During the wear of the blinded sensor, it is necessary to measure blood glucose by fingerprick two times a day for calibration. If a participant already uses a CGM of Medtronic, no blind sensor wear is necessary because then the same CGM as the intervention arm is already in use. Performing a finger prick for glucose measurement can be somewhat painful, however contains no risk.

the current study can only be carried out in this specific population. Potentially the participant benefits from the intervention through improvement of glucose values and quality of life. The 780G closed loop system is already used by patients with diabetes mellitus type 1 with great satisfaction and improvement of glucose values and quality of life in the majority of users.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

• Women with T1DM, diagnosed at least 1 year before pregnancy
• Age 18-45 years
• A singleton pregnancy confirmed by b-HCG in blood and/or ultrasound-confirmed gestational age up to 11 weeks and 6 days.
• Treated with intensive insulin treatment (either MDI, insulin pump). A closed-loop system can only be used in manual mode.
• HbA1c level <=10%.
• Participants need to speak and understand Dutch or English and have e-mail access.

Exclusion criteria

• The use of a closed-loop insulin delivery system in auto mode.
• A twin (multiple) pregnancy
• A physical or psychological disease likely to interfere with the conduct of the study (based on the evaluation by the treating physician)
• Medications known to interfere with glucose metabolism
• A daily insulin dose of >=1.5 units/kg
• Known allergy to adhesives due to infusion set and/or continuous glucose monitor

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2022
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	MiniMed 780G Insulin pump
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	24-11-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-08-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04520971
CCMO	NL78535.000.21