Effectiveness of continuous glucose monitoring during diabetic pregnancy

Published: 19-04-2011
Last updated: 04-05-2024

In the present proposal, we aim to assess the cost-effectiveness of the use of CGMS in diabetic pregnancies.

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

Summary

ID

NL-OMON38017

Source
ToetsingOnline

Brief title
Continuous glucose monitoring in diabetic pregnancies

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Maternal complications of pregnancy

Synonym
diabetes mellitus, gestational diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: diabetes mellitus, fetal macrosomia, gestational diabetes, pregnancy

Outcome measures

Primary outcome

Primary outcome of the RCT will be macrosomia rate, defined as a birth weight above the 90th centile.

Secondary outcome

Secondary outcomes will be birth weight, composite neonatal morbidity, maternal outcome and costs. The analyses will be according to the intention to treat principle.

Study description

Background summary

Hyperglycemia in pregnancy is associated with poor perinatal outcome. Even if pregnant women with diabetes are monitored according to current guidelines, they do much worse than their normoglycemic counterparts. The Continuous Glucose Monitoring System (CGMS) is an efficacious new method to optimize glucose control in pregnant women with diabetes.

Study objective

In the present proposal, we aim to assess the cost-effectiveness of the use of CGMS in diabetic pregnancies.

Study design

Multicenter open label randomized clinical trial (RCT) with a decision and cost-effectiveness study alongside it.

Intervention

Participating women will get either addtional use of CGMS or care as usual. All

women will check their blood glucose by daily monitoring and HBA1c-values. For the women in the CGMS group monthly use of the CGMS will be added. Their inulinescheme will be adjusted according to the CGMS-profiles.

Study burden and risks

The risks of participation in this trial are considered to be negligible. Participants who are randomised for use of the CGMS might benefit from it. Participants who are randomised for standard care might not benefit from this trial in this pregnancy, but their participation is indispensable for the well being of future diabetic pregnant women and their children. All participants fill out three questionnaires, which will take them approximately 30 minutes per questionnaire. Furthermore, participants who are randomised for the CGMS will have the device placed and removed during regular visits with their doctor and wear the sensor and the monitor during 5-7 days each time, with a maximum of 5 times.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Pregnant women with pre-existing diabetes (type 1 or type 2) before 16 weeks of pregnancy or with gestational diabetes before 30 weeks of pregnancy;
- on insulin treatment regimen or use of insulinpump;
- who are 18 years or older.

Exclusion criteria

- Severe medical or psychological comorbidity
- Multiple pregnancies

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2011
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	19-04-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL33801.018.10