Improving preconceptional glycaemic regulation using RealTime Continuous Glucose Monitoring in women with type 1 diabetes who have *acceptable but not optimal* HbA1c values: an observational study

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This study is designed to investigate whether it is possible to achieve substantial improvement in HbA1c values using RT-CGMS in women with type 1 diabetes with acceptable but not optimal glycaemic control in preconceptional period (which is HbA1c...

Ethical review	Not approved
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON35863

Source
ToetsingOnline

Brief title
Improving preconceptional glucose regulation in DM1women using RT-CGMS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes, Diabetes Mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diabetes type 1, glucosemonitoring, preconceptional, real-time

Outcome measures

Primary outcome

Primary outcome - Absolute reduction in HbA1c

Secondary outcome

Secondary outcomes

- Incidence of severe hypoglycaemia

- Percentage of women with a fall in HbA1c of >= 5 mmol/mol

- number of consultations (by telephone, internet, on the out-patient clinic)

- Change in glycaemic variability

- Composite end point: reduction of HbA1 >= 5 mmol/mol without an episode of

severe hypoglycemia

- Frequency of use RT-CGMS - Fear of hypoglycaemia - Quality-of-life -

Satisfaction with the device.

Study description

Background summary

Despite major advances in diabetes care the incidence of adverse pregnancy outcomes in women with type 1 diabetes mellitus is still significantly higher than in non-diabetic pregnancies. It is has been established that suboptimal

glucose regulation is associated with adverse pregnancy outcomes. Therefore there is general consensus that prepregnancy care and optimal glycaemic control as well as during pregnancy is mandatory to achieve the best possible pregnancy outcome in these women with HbA1c as the parameter available reflecting the quality of glycaemic control. The latest guidelines state that we should aim for a preconceptional HbA1c-level as near the normal range (below 43 mmol/mol, 6.1%) as possible to achieve the best outcomes. However, lowering the HbA1c-level towards the normal range can cause an increases risk of (severe) hypoglycaemia increases, often posing a barrier to reach optimal control. As a compromise, an HbA1c level less than 53 mmol/mol (7.0%) is accepted as good enough to become pregnant. It was thought that glycaemic control with an HbA1c <53 mmol/mol was associated with rates of malformations no greater than those in pregnancies in non-diabetic women. Recent studies have indicated that there is probably still a residual extra risk in this situation.
This is this basis for the quest for possibilities to achieve the lowest possible Hba1c-level without excess hypoglycaemia.
Glucose monitoring by self-measurement of glucose levels in capillary blood is an important part of the day-to-day management of diabetes and a cornerstone of treatment. But self -measurement of blood glucose levels does on provide snapshot images, limiting the possibilities to improve glycaemic control.
Real-Time Continuous Glucose Monitoring System (RT-CGMS) allows instantaneous display of actual glucose values combined with an alert-function when glucose levels or changes in levels fall outside preset individualised limits. Studies have shown that RT-CGMS can improve glycaemic control or sustain adequate control in patients with type 1 diabetes without increasing hypoglycaemic episodes, also in well-regulated patients. However studied populations were heterogenic and no studies have been done with RT-CGMS during the preconceptional period; the population of this study.
In November 2011 College Voor Zorgverzekeringen (CVZ) decided to approve reimbursement RT-CGMS for specific groups of diabetic patients including pregnant women but not in preconceptional women because of a lack of studies in this particular group

Study objective

This study is designed to investigate whether it is possible to achieve substantial improvement in HbA1c values using RT-CGMS in women with type 1 diabetes with acceptable but not optimal glycaemic control in preconceptional period (which is HbA1c between 47-53 mmol/mol).

Primary outcome
- Absolute reduction in HbA1c
Secondary outcomes
- Incidence of severe hypoglycaemia
- Percentage of women with a fall in HbA1c of >= 5 mmol/mol
- number of consultations (by telephone, internet and in out-patient clinic)
- Change in glycaemic variability

- Composite end point: reduction of HbA1 >= 5 mmol/mol without an episode of severe hypoglycaemia
- Frequency of use RT-CGMS
- Fear of hypoglycaemia
- Quality-of-life
- Satisfaction with the device

Study design

This is a 16-week non-randomised intervention, single centre, single-arm, exploratory study analyzing the effect of RT-CGMS use in preconceptional women with diabetes type 1 women who have acceptable but not uptimal regulated blood sugars.

Setting:
The study will be carried out in the setting of the already longstanding collaborative group of the UMC Utrecht Departments of Internal Medicine and *Vrouw en Baby*. This group has founded in the nineties a joint Obstetrics-Internal Medicine clinic for pregnant patients with any kind of diabetes which has served as a role model for other institutions.

Approach of patients:
every women with suboptimal regulated type 1 diabetes mellitus who is treated at the out-patient clinic for Diabetology of the UMC Utrecht and who has a child wish will be approached for this study

Interventie:
Medical consultation by:
- Diabetes nurse educator (scheduled every two weeks, plus possibility of 24h a day by telephone or email)
- Diabetes specialist (scheduled week 0, week 1, week 4, week 8, week 12, week 16)
Every therapy change will be made under supervision (from nurse to research physician to supervising physician) and noted
Intervention:
- Questionnaires every 4 weeks
- RT-CGMS during 7 consecutive days every other week (in total: 8 of 16 weeks)
Results will be used for counseling / treatment adjustments
3 times blinded RT-CGMS for 48 hours in week 0 and 16 and 20

Standard therapy:
- Insulin pump therapy (replaced by RT_CGMS: insulin pump and glucose sensor in one)
- SMBG at least 5 times a day for at least 5 days a week
- Standard blood controls:
HbA1c and fructosamine every 4 weeks
TSH and FT4, cholesterol, Hb, Kreatinine and urinesediment at baseline

Post study:
=> Patients will be offered to use RT-CGMS after end of study until eventually pregnancy. At that moment they can obtain RTCGMS as regular, reimbursed treatment

Intervention

RT-CGMS during 7 consecutive days every other week (in total: 8 of 16 weeks)
Results will be used for counseling / treatment adjustments

Study burden and risks

Participation with this trial can be a burden on some fronts:
- Some patients have to change physician (namely the research-physician with supervision of the specialist who is concerned with the diabetic care of pregnant women). However, when they get pregnant (although not participating this study) they then also become under the supervision of the named specialist because this is common care in pregnant diabetes patients in the UMC Utrecht.
- The use of RT-CGMS can be a burden because the alert-function, besides the advantage of the warning possibilities, causes unpredictable disturbances of daily (meetings, visits, shopping etc) or nocturnal (sleeping) activities.
- Patients will have to connect the RT-CGMS themselves (every other week) and will have to replace the needle after 3 days of use
- Patients always have to confirm glucose values given from the RT-CGMS with SMBG before making therapy adjustments
- Former studies showed some possible skin irritative adverse affects from (RT-)CMGS use
- We will ask patients to fill in some questionnaires every 4 weeks
- Risk of hypoglycaemic events. It is possible that there will be hypoglycaemic events during this trial. However, we expect that the incidence during this study is as high or even less high as in common care. In common care one should also aim for the lowest glucose levels. In this study, by using RT-CGMS, the alert-function has the potential to early warning for, and therefor preventing, a hypoglycaemic episode. A systematic review of 7 RCT studies using devices (Hoeks et Greven, 1 april 2011 Diabetic Medicine) describes that 6 of 7 studies did not show an increase in hypoglycaemic events. One study did show an increase in severe hypoglycaemia (however the authors reported that this was because of non-use and/or incorrect use of the device. Two studies showed a decrease in HbA1c in absence of severe or non-severe hypoglycemia in the RT-CGMS group. No study was powered enough to demonstrate a decrease in hypoglycaemic events.

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

- diagnosed with diabetes mellitus 1 at least for one year diagnosis
- insulin pump for at least 3 months
- reliable performance of SMBG at least 5 times a day for at least 5 days a week
- child wish
- stable HbA1c 43-53 mmol/mol: the last 2 values +/- 3 mmol/mol
- willing to (patient herself) and capable of (as estimated by treating doctor) using RT-CGMS
- able to read and speak Dutch
- written informed consent
- internet access (uploading results sensor)

Exclusion criteria

- co-existent medical problems that would interfere with study participation
- use of medication that could influence glycaemic control (for example corticosteroids) in

last three months

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	RealTime-Continuous Glucose Monitoring System
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	19-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37048.041.11
Other	TC = 2742 (NTR)