MaxABC study: effect of Automated Bolus Calculation on glycemic variability and relation with psychological problems. Pilot study.

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

Summary

ID

NL-OMON41020

Source
ToetsingOnline

Brief title
MaxABC study - Pilot

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: onderzoek wordt uit eigen midelen gefinancieerd

Intervention

Keyword: automated bolus calculation, diabetes mellitus, glycemic control, Psychological problems

Outcome measures

Primary outcome

The purpose of the present study is to test whether a structured Bolus Calculation education program and subsequent use of the Accu-Chek® Aviva Expert with an integrated bolus advisor can improve glycemic control in carbohydrate counting-patients with type 1 or type 2 diabetes mellitus with suboptimal glycemic control. Additionally, we will asses if the BolusCal concept leads to improvements in various patient reported outcomes such as quality of life, treatment satisfaction and fear of hypoglycemia.

Secondary outcome

To determine if measurements of daily glucose levels are associated with psychological factors (mood, anxiety, energy level). And if so, which glucose measurements are related to which psychological factors

To determine if, in case an association is found for the question above, the type of diabetes is an effect modificator.

To determine if patients with depressive disorders and/or other long term psychological problems have greater glucose fluctuations or other differences in glucose measurements.

Study description

Background summary

Diabetes mellitus is a chronic condition with a major impact on day-to-day life. Optimal glycemic control is very important for reducing risk of complications but requires a high degree of self-management for patients on insulin therapy. Carbohydrate counting combined with a structured education program can help improve glycemic control. For this reason the BolusCal Education program has been launched in the Netherlands for diabetes patients on multiple daily injection therapy.
Until recently, the best measure of glycemic control was HbA1c. Nowadays we can measure glucose control with continuous glucose monitoring. A validated interpretation of these measurements however is not yet available. Moreover, it is still unclear to what extent fluctuations in blood glucose levels are related to various psychological factors concerning quality of life. In order to optimize diabetes treatment, further insight has to be gained in the impact of daily glucose regulation on various aspects of patients* well-being.

Study objective

The purpose of the present study is to test whether a structured Bolus Calculation education program and subsequent use of the Accu-Chek® Aviva Expert blood glucose meter with an integrated bolus advisor can improve glycemic control in diabetes patients. We will also asses if the BolusCal concept leads to improvements in various patient reported outcomes concerning quality of life and if this is related to measures of glucose control as measured with continuous glucose measurement.

Study design

single center 16-week intervention pilot study

Intervention

study subjects will participate in the BolusCal education program: a structured program concerning insulin dose adjustment based on carbohydrate counting with the use of a personalized automated bolus calculator.

Study burden and risks

There are no direct benefits for study subjects. The BolusCal program is considered regular care and is therefore also available to patients who chose not to participate in this study.

Risk associated with this study is minimal. Risk of infection at insertion of the sensor needle is present but low. Risk of hypoglycemia is minimal and not increased compared to regular care.
The burden for the patient consists of carrying the CGM sensor twice for a week. During CGM, patients will fill out a lifestyle diary. Psychological questionnaires have to be filled in twice. During the entire study a hypoglycemia diary will be kept and glucose will be measured 4 to 7 times a day. 6 hospital visits in 16 weeks are necessary for participation. Blood is drawn twice at baseline and 16 weeks for HbA1C measurement.

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

* Subject is * 18 years of age.

* Patient is diagnosed with Type 1 or Type 2 diabetes, with an HbA1c in the range of 48-86 mmol/mol, with either multiple hypoglycemia episodes (defined as >1 per month) or large daily variability. HbA1c has remained stable within a range of 12 mmol/mol in the year prior to inclusion.
* Subject has had diabetes for >12 months.
* Subject has been on Multiple Daily Injections (MDI) insulin therapy for at least 6 months
* Subject adjusts meal insulin doses based on carbohydrate content of meals.
* Subject is sub-optimally controlled at investigator*s discretion.

Exclusion criteria

* Subject has been diagnosed with any clinically significant condition at investigator*s discretion e.g. infectious disease, major organ system disease, Gastroparesis, Psychosis or cognitive impairment, severe or moderate renal impairment, defined by an eGFR <50ml/m/1.73, active proliferative retinopathy.
* Subject is on chemotherapy or radiation therapy (self-reported)
* Subject is pregnant, breast feeding or currently planning a pregnancy (self-reported).
* Patient is unable to work with a PDA and or smartphone at investigator*s discreation.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	aviva expert

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-10-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
Other	aangevraagd
CCMO	NL48235.015.14