MaxABC study: Effect of Automated Bolus Calculation on glycemic variability and relation with psychological problems

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25007

Source
NTR

Brief title
sensor BolusCal glucose variabillity welbeiing

Health condition

sensor BolusCal glucose variabillity welbeiing

Sponsors and support

Primary sponsor: Maxima Medical Centre
ds th Fliednerstraat 1
5631 BM Eindhoven

Source(s) of monetary or material Support: own research centre and educational grant Roche

Intervention

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 and / 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 daily fluctuations in blood 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 question 2, 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

Study design

none

Intervention

BolusCal educational program an sensor

Contacts

Public
Diabetesverpleegkundige
Research verpleegkundige
H. Vroenhoven, van
Maxima Medical Centre
Ds. Th. Fliednerstraat 1
Eindhoven 5631 BM
The Netherlands
040-8885548
Scientific
Diabetesverpleegkundige

Research verpleegkundige
H. Vroenhoven, van
Maxima Medical Centre
Ds. Th. Fliednerstraat 1
Eindhoven 5631 BM
The Netherlands
040-8885548

Eligibility criteria

Inclusion criteria

• Subject is ≥ 18 years of age.

• Patient is diagnosed with Type 1 or Type 2 diabetes.

• HbA1c lies in the range of 48-86 mmol/mol, with either multiple hypoglycemia episodes or large variability as measured by blood glucose self-measurements and participating in the structured BolusCal Education program. 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, consisting of 1-2 injections per day of long-acting basal insulin (Lantus® or Detemir®) and at least 2 injections per day of regular or rapid-acting analogue insulin for meal coverage.

• Subject adjusts meal insulin doses based on carbohydrate content of meals.

• Subject is sub-optimally controlled at investigator’s discretion.

• Patient has the willingness to measure his/her blood glucose level four to seven times a day for a period of 6 months.

• Patient’s Dutch language skills are sufficient for participation in the BolusCal program at investigator’s discretion.

Exclusion criteria

• Subject has been diagnosed with any clinically significant condition at investigator’s discretion e.g.:

o Infectious disease,

o Major organ system disease,

o Gastroparesis

o Psychosis or cognitive impairment,

o Severe or moderate renal impairment, defined by an eGFR <50ml/m/1.73,

o Active proliferative retinopathy.

• Subject is on chemotherapy or radiation therapy (self-reported)

• Subject is pregnant, breast feeding or currently planning a pregnancy.

• Patient is unable to work with a PDA or smartphone, at investigator’s discreation.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-07-2014
Application type:	First submission

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
NTR-new	NL4562
NTR-old	NTR4730
Other	METC Maxima Medisch Centrum : 1436

Study results