

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

Gepubliceerd: 18-07-2014 Laatste bijgewerkt: 18-08-2022

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25007

Bron

NTR

Verkorte titel

sensor BolusCal glucose variability welbeing

Aandoening

sensor BolusCal glucose variability welbeing

Ondersteuning

Primaire sponsor: Maxima Medical Centre

ds th Fliednerstraat 1

5631 BM Eindhoven

Overige ondersteuning: own research centre and educational grant Roche

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Onderzoeksopzet

none

Onderzoeksproduct en/of interventie

BolusCal educational program an sensor

Contactpersonen

Publiek

Diabetesverpleegkundige

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

Wetenschappelijk

Diabetesverpleegkundige

Research verpleegkundige
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Eindhoven 5631 BM
The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 discretion.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	18-07-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4562
NTR-old	NTR4730
Ander register	METC Maxima Medisch Centrum : 1436

Resultaten