ECSPECT-HYPO trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29063

Source
Nationaal Trial Register

Brief title
ECSPECT-HYPO

Health condition

Diabetes type 1, Hypoglycaemia, Impaired awareness of hypoglycemia, Continuous glucose monitoring, Psychoeducation.

Diabetes type 1, Hypoglycaemie, Hypoproblematiek, Continue glucose monitoring, Psychoeducatie.

Sponsors and support

Primary sponsor: Vrije Universiteit Medical Center
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Frequency of (self-reported) severe hypoglycemia

Secondary outcome

Hypoglycemia awareness (Gold score); frequency of mild hypoglycemia; glycosylated hemoglobin (HbA1c); results from the diagnostic glucose sensor: time spent in the euglycemic range (interstitial glucose >3.9-<10.0 mmol/L), sensor-derived hypoglycaemic events, nocturnal hypoglycemia, area under curve (AUC) ¡Ü3.9 mmol/L and glucose variability; psychological well-being: fear of hypoglycemia (Hypoglycemia Fear Survey (HFS-II)), diabetes-related distress (PAID); quality adjusted life years (QALYs) and societal costs consisting of costs of healthcare consumption, informal care and lost productivity.

Study description

Study objective

A stepped-care approach starting with HypoAware intervention, with eventual additional continuous glucose monitoring (CGM), is more (cost-)effective compared with CGM only in type 1 diabetes patients with an impaired awareness of hypoglycemia.

Study design

Baseline, 3, 6, 12 months

Intervention

- Continuous glucose monitoring (CGM)

- Stepped Care: starting with HypoAware (step 1), a psycho-educational programme, and later adding CGM if needed (step 2)

Contacts

Public
C. Racca
Amsterdam
The Netherlands
Scientific
C. Racca
Amsterdam
The Netherlands

Eligibility criteria

Inclusion criteria

- 18 years or older

- Type 1 diabetes, treated with either continuous subcutaneous insulin infusion (CSII) or multiple daily insulin injections (MDI)

- Impaired awareness of hypoglycemia, as defined by Gold criteria (i.e., with a Gold score >=4) and one or more severe hypoglycemic events (defined as events requiring external assistance) the past two years

Exclusion criteria

- Renal insufficiency, with glomerular filtration rate (GFR) < 30 mL/min

- History of myocardial infarction in the last 3 months

- Current untreated proliferative diabetic retinopathy

- Current (treatment for) malignancy

- Current psychiatric disorders

- Current substance abuse or alcohol abuse (men >21 units/week, women >14 units/week)

- Pregnancy or pregnancy wish

- Current use of FreeStyle Libre, acquired < 3 months prior to screening for problems with hypoglycemia¡¯s

- Any hearing or vision impairment that could hinder perception of the glucose display and alarms, or otherwise incapable of using a (RT-)CGM, in the opinion of the investigator

- Poor command of the Dutch language or any (mental) disorder that precluded full understanding of the purpose and instructions of the study

- Any known or suspected allergy to trial-related products

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018
Enrollment:	115
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48870
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6619
NTR-old	NTR6949
CCMO	NL64474.029.18
OMON	NL-OMON48870

Study results