Current state of impaired awareness of hypoglycaemia (IAH) in people with type 1 diabetes; change in prevalence, impact of glucose monitoring technology and psychosocial impact

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The primary objective is to investigate the current prevalence of IAH and severe hypoglycaemia (SH) in individuals with diabetes type 1.The secondary objectives are:- Study the change of IAH over time in individuals with diabetes type 1.- Study risk...

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

Summary

ID

NL-OMON48008

Source
ToetsingOnline

Brief title
Current state of IAH in people with type 1 diabetes

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, Insulin-Dependent Diabetes Mellitus 1

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: HypoResolve project;project welke wordt gesubsidieerd door de Europese Unie

Intervention

Keyword: Diabetes type 1, Glucose monitoring technology, Hypoglycemia, Impaired awareness of hypoglycemia

Outcome measures

Primary outcome

The main study parameter will be the current prevalence of IAH and SH.

Secondary outcome

The secondary study parameters will be:

- Frequency of IAH change over years.

- Difference in frequency of IAH/SH (new cases, changes in IAH state) in

individuals who use RT-CGM/FGM compared to those who use traditional glucometer.

- Odds ratio of factors contributing to development/prevention of SH/IAH change

over time.

- Answers to different (qualitative, quantitative) questionnaires (see

appendix).

Study description

Background summary

Hypoglycaemia is the most frequent complication of insulin treatment in individuals with type 1 diabetes and a limiting factor for achieving optimal glycaemic control. Recurrent, hypoglycaemia can induce a process of habituation, leading to impaired awareness of hypoglycaemia (IAH). In the past 5-10 years, the use of continuous real-time (RT-CGM) or flash glucose

monitoring (FGM) has increased rapidly in people with type 1 diabetes to improve overall glycaemic control and reduce the frequency of hypoglycaemic events. So far, there is no evidence that either RT-CGM or FGM improves IAH in subjects with type 1 diabetes, despite a decrease of severe or sensor-measured hypoglycaemia. It thus remains to be established whether chronic use of continuous glucose monitoring devices impacts on the prevalence of IAH in people with type 1 diabetes. Given a number of changes in clinical care, including increased use of RT-CGM and FGM as described above, it becomes highly appropriate to investigate the current state of IAH and severe hypoglycaemia in type 1 diabetes. Also, since invites to this study will specifically include people who have taken part of previous assessments, this study wll be able to investigate the change in IAH over time and the potential contributing role of RT-CGM/FGM. Furthermore, we want to explore associations of IAH and severe hypoglycaemia with clinical parameters, quality of life and psychosocial impact. This knowledge will help people with diabetes and their healthcare providers to better adjust treatment recommendations to individual targets.

Study objective

The primary objective is to investigate the current prevalence of IAH and severe hypoglycaemia (SH) in individuals with diabetes type 1.

The secondary objectives are:
- Study the change of IAH over time in individuals with diabetes type 1.
- Study risk factors associated with change of IAH over time.
- Assess the role of RT-CGM/FGM on (change of) IAH and SH.
- Study thoughts, emotions and worries which lead to a certain behaviour in case of hypoglycaemia and prevention of hypoglycemia.
- Study associations of IAH and history of SH with productivity in different situations (work/study, relation/sexuality, driving behaviour/traffic and sport/leisure).
- Study association between partner involvement and handling in case of (unawareness for) hypoglycemia.
- Study knowledge of subjects with diabetes about hypoglycemia and IAH.
- Study burden of IAH and severe hypoglycaemia on family members of people with type 1 diabetes, as experienced by patients themselves.

Study design

This study will be a cross-sectional observational cohort study. The study will be conducted at the Radboud university medical center, department of internal medicine. Subjects with type 1 diabetes will be recruited from outpatient diabetes clinic as well as subjects who participated in two earlier cohorts and agreed to be approached again.

Study burden and risks

The subjects will not benefit directly from participation to the study. Irrespective of the outcome of the trial, it will provide useful information about hypoglycaemia, IAH, benefits of glucose monitoring systems and psychosocial effects of diabetes, hypoglycaemia and IAH. The results of the trial will thereby provide physicians and patients new relevant information towards a better healthcare for the individuals with diabetes. The only risk we expect in our study is associated with blood sampling. This procedure may lead to (small) hematomas or temporarily pain, yet these are self-limiting. There are no other risks.

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

- Diabetes mellitys type 1

- Age *16 years
- Ability to provide written informed consent
- Fluency in speaking and reading Dutch

Exclusion criteria

- Severe psychiatric comorbidity
- Other comorbidity interfering with completing surveys, as judged by the healthcare professional

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2021
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-07-2020
Application type:	Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL71207.091.19