Hypo-METRICS: Hypoglycaemia - Measurement, ThResholds and ImpaCtS;A clinical study to Determine the Optimal Threshold and duration of low interstitial glucose events that have an impact on patient experienced hypoglycaemia, quality of life and health economic outcomes.

Published: 06-07-2020
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The overall aim of this study is to better understand the impact of symptomatic and asymptomatic episodes of hypoglycaemia on people living with diabetes.

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

Summary

ID

NL-OMON49518

Source
ToetsingOnline

Brief title
Hypo-METRICS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

Diabetes mellitus, ''sugar disease''

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Europese Unie,Innovative Medicines Initiative 2 Joint Undertaking (IMI),The Leona M and Harry B. Helmsley Charitable Trust (HCT)

Intervention

Keyword: Continuous glucose monitors (CGM), Diabetes mellitus, Impact hypoglycemia

Outcome measures

Primary outcome

Determine the Low Interstitial Glucose (LIG) parameters that have the optimum

performance for detection and identification of patient-reported-hypoglycemia

(PRH); *LIG*_PRH (h_opt,t_opt).

Secondary outcome

Impact of symptomatic and asymptomatic hypoglycaemia on different domains of

Quality of Life (QoL) and health economic variables.

Study description

Background summary

Hypoglycaemia or low blood glucose, and its fear are major barriers to achieving optimal glucose control. New technology, such as continuous glucose monitors (CGM), help us to better identify hypoglycaemia and develop strategies to avoid it. These devices measure glucose in the skin, rather than in the blood, and provide information not only on how low glucose is, but also for how long. Recent studies showed that over half of episodes of low glucose with these systems are not recognised by people with diabetes, and even people without diabetes have sensor values that are below the current thresholds for hypoglycaemia [low blood glucose] that we measure with traditional monitors. In this study, we will evaluate the impact of symptomatic as well as

asymptomatic episodes of low sensor glucose on a variety of clinical, patient related and health economic outcomes such as mood, quality of sleep and productivity. We will test different levels and durations of low sensor glucose to identify the one that best matches episodes that are symptomatic to help us best define hypoglycaemia using these systems.
We will also look at factors that influence this such as sleep or activity as well as diabetes management behaviours (such as insulin dosing, carb counting, etc). At the end of this study, we will be able to provide a better definition of clinically relevant low sensor glucose readings that we hope will help inform clinical as well as academic interpretation of CGM data.

Study objective

The overall aim of this study is to better understand the impact of symptomatic and asymptomatic episodes of hypoglycaemia on people living with diabetes.

Study design

This is a multinational multicentre observational study designed to identify the continuous glucose monitoring parameters [threshold and duration] that best correlate with episodes of patient reported hypoglycaemia.
We will also then look at the impact of these episodes of hypoglycaemia on biological, quality of life and health economic outcomes.

Participants will be recruited from 8 centres across Europe and after informed consent, will complete a series of baseline questionnaires and baseline blood samples. They will undergo 10 weeks of blinded continuous glucose monitoring during which they will use a bespoke app on a smartphone to answer questions about any hypoglycaemia they may have experienced, along with questions about various domains of quality of life and productivity that may be affected by diabetes. The app will ask them this series of questions once on waking, once in mid-afternoon and once before bed, every day. During the study period, they will continue with usual diabetes management and their usual method of glucose monitoring. They will also wear an activity tracker that will provide information on their sleep and activity.

Data will be anonymised and downloaded onto the study database at the end of the 10-week period for analysis. Participants will be seen once more, 1 year after recruitment to repeat the questionnaires they completed at baseline. We will also collect some blood samples at their three main visits.

Study burden and risks

The trial will be conducted in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures. A risk assessment and monitoring plan will be prepared before the study opens and will be

reviewed as necessary over the course of the trial to reflect significant changes to the protocol or outcomes of monitoring activities.
This is a very low risk study in which an adverse event occurring as a direct consequence of taking part in the study is unlikely as there is no intervention. Wearing a glucose sensor can be minimally irritating (skin irritation due to adhesion film, bruising when inserting the sensor), but these devices are being used in routine diabetes care with minimal problems.
Monitoring one's hypoglycaemia events and quality of life on a smart phone app may be a new experience for some. This level of self-reflection may cause distress but at the same time may help in discussing diabetes problems with the clinicians more effectively.
Data protection: all downloads from devices (CGMS and App) will be anonymised, as it will be the case for all data obtained in this study.

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

1. Age 18 - 85 years
2. HbA1c 5 * 10% [31 * 86 mmol/mol]
3. Confirmed diagnosis of type 1 or type 2 diabetes
4. Using > 1 injection of insulin / day or insulin pump.
5. Ability to provide written informed consent
6. Performing regular SMBG [> 1 / day on a 4-week download] . For those using flash or continuous glucose monitoring, this should be used at least 70% of the time.
7. At least 1 episode of hypoglycaemia [either biochemical or symptomatic] in the last month
8. On stable therapy for at least 3 months.
9. Willing to complete study procedures including wearing the Fitbit and CGM devices and completing the EMA questionnaires on the uMotif app three times a day for 10 weeks (we expect minimum 80% data completeness)

Exclusion criteria

1. Concurrent conditions that can affect glucose readings [renal impairment GFR < 30 ml/min, hepatic impairment, untreated adrenal or thyroid insufficiency, as judged by the investigator.
2. Severe cognitive impairment or psychological illness that can impair performance of EMA tasks, visual impairment that will preclude use of the EMA or sensors.
3. Severe psychiatric / psychological illness including extreme fear of hypo- or hyper- glycaemia (in the opinion of the investigator)
4. Pregnant or plans for pregnancy in the next 6 months
5. Use of automated insulin delivery systems such as closed loop or automated threshold suspend or predictive low glucose suspend insulin pumps.
6. Known allergies to adhesives required for the CGM systems
7. People who work regular night shifts
8. Any other condition which in the opinion of the study team would impair their ability to complete the study

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-01-2021
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	Freestyle Libre;uMotif app and Fitbit Charge 3
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-07-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-11-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-02-2022
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	NL73044.091.20
Other	Volgt