Algorithm update study for the Inreda AP

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Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57688

Source
Onderzoeksportaal

Brief title
Onderzoek AP6 update

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Type 1 diabetes, insulin dependent diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Inreda Diabetic
Source(s) of monetary or material Support: Inreda Diabetic

Intervention

- Medical device

Explanation

N.a.

Outcome measures

Primary outcome

The main study parameter is the time spent in blood glucose range (3.9 – 10 mmol/L) on the updated software algorithm during the main study. It is hypothesized that this time spent in range is at least as high in the updated software algorithm compared to the regular AP algorithm.

Secondary outcome

Secondary safety parameters are: Normal hypo- and hyperglycemia event rate Extended hypo- and hyperglycemia event rate Adverse events Device issues Secondary performance parameters are: The proportion of time spent in range (3.9 – 10 mmol/L) during the feasibility tests
The proportion of time spent in the following ranges: Hypoglycemia level 2 (TBR2) (<3.0 mmol/L)
Hypoglycemia level 1 (TBR1) (<3.9 & >3.0 mmol/L)
Time in tight range (TITR) (3.9 – 7.8 mmol/L)
Hyperglycemia level 1 (TAR1) (>10 & <13.9 mmol/L)
Hyperglycemia level 2 (TAR2) (>13.9 mmol/L)
TIR, TITR, TAR1, TAR2, TBR1, TBR2 during the day and night
The day period is defined as the time between 06:00 and 24:00 and the night period is defined as the time between 24:00 and 06:00.
TIR, TITR, TAR1, TAR2, TBR1, TBR2 during activity
Activity periods will be established based on AP transmitter accelerometer data in combination with information provided by the participants about their exercising habits. Mean or median glucose concentration
Mean or median glucose concentration during the day and night
Mean or median glucose concentration during activity Change in Glucose Management Indicator (GMI)
Glycemic variability
Coefficient of variation Interquartile range Secondary AP parameters are: Daily insulin and glucagon usage. For the main study, in addition to the secondary safety, performance and AP parameters above, the following secondary parameters will also be evaluated: Percentage of patients achieving treatment goals: >70% TIR and/or <4% TBR
Expectations, trust and treatment satisfaction using DMSRQ

Study description

Background summary

Inreda Diabetic B.V. developed a bi-hormonal artificial pancreas (AP) to provide automated glycemic control for insulin treated adult subjects with type 1 diabetes. The Inreda AP is CE-certified since February 2020. Different clinical studies (called APPEL 1 to 5: 'Algorithm to control Postprandial, Post exercise and night glucose Excursions in a portable closed Loop format') were performed to evaluate feasibility, safety and performance of the device. These studies facilitated market approval of the AP of Inreda Diabetic BV. However, recent post-market surveillance data from the period of October 2023 – September 2024 showed a deterioration in outcome measures compared to the previous year. Additionally, a survey revealed that patients perceive that the AP is not (yet) able to regulate blood glucose completely independently in all situations and at all times. Therefore, patients often feel the need to make adjustments in their eating and drinking habits and/or insulin injections. With these most recent outcome measures and user experiences in mind, Inreda Diabetic is currently working on a new model of the AP, the AP6. One of the main goals of the AP6 is to create a more user-friendly device. This is accompanied with an update in the software algorithm, which could potentially improve the diabetes management of the AP users. One of the main changes in the software algorithm is the addition of new features, of which some will be made adjustable per individual. In order to implement the updated software algorithm, the best settings and design choices in this algorithm need to be determined, and the performance and safety of the updated software algorithm needs to be verified using clinical data.

Study objective

The primary objective of the study is to assess the performance of the updated algorithm software. The secondary objectives are to assess the safety and other performance parameters of the updated software algorithm. Additionally, another secondary objective is to assess if and which of the new features in the updated software algorithm are valuable for the patients, and whether these need to be adjustable per individual or can be universal.

Study design

The study will consist of two parts: the feasibility tests and the main study. In the feasibility tests, participants will test the new features. These include an adjustable target value and recurring and flexible time frames in which the insulin dosage is different with respect to the basal insulin dosage. The results of the feasibility tests determine the superior version of the updated software algorithm that will be used throughout the main study. The main study is a randomized crossover study in which participants will be using the updated software algorithm for 4 weeks, of which 2 weeks of data will be collected. This will be compared to the regular AP algorithm, of which also 2 weeks of data will be collected.

Intervention

The investigational product is the updated software algorithm to be used in the AP system of Inreda Diabetic. This updated software algorithm will be implemented in the current CE-marked AP system, the AP5. The participants in this study are already using the AP5 as their current diabetes management. The effects of the updated software algorithm on glycemic control and general diabetes treatment will be evaluated with respect to the regular software algorithm.

In the updated software algorithm, new features will be introduced that will be personalized to the individual to achieve improved glycemic control. These features are an adjustable target and recurring and flexible time frames in which the insulin dosage can be altered with respect to the basal insulin settings.

The target value is a pre-defined 'optimal' blood glucose value that the AP strives at achieving. In the current software algorithm, this target value is fixed for all individuals. However, this fixed target value might not be optimal for all individuals. In this study, the researcher will determine the optimal target value, based on the participant's medical history, glucometrics (primarily TIR, TBR, and mean glucose), personal preferences, and other baseline characteristics. This target value can be higher, lower, or similar to the original value.

The second type of features evaluated in this study are time frames. In these time frames the insulin setting can be set either higher or lower compared to the basal insulin settings. The purpose of this time frame mode is to get better control over foreseeable/plannable high or low glucose levels. Two types of time frames are evaluated: recurring time frames and flexible time frames. The recurring time frame will repeat every day. The time will be set by the participant, and the settings within this time frame are either lower or higher with respect to the basal settings. The flexible time frame is not recurring and the time frame needs to be set by the participant every time they want to use it.

Study burden and risks

The participants need to visit the clinical research center twice, at the start and at the end of the study. Additionally, they will be called frequently. Thus, participating in this study requires extra time and effort for the participants. The risk associated with this study is the failure of the updated software algorithm to control the glucose levels, causing hypo- or hyperglycemia. However, the updated software algorithm builds on the current algorithm, which is in use in daily practice over four years after having been validated in clinical trials. Additionally, the algorithm has a built-in safety mechanism. At any time, the safety mechanism will prevent that the defined maximum insulin and glucagon doses per time unit are exceeded. The participants in this study use the AP as their standard diabetes treatment. Therefore, they are familiar with operating the AP and the safety issues that are associated with a 'diabetes life'. Additionally, participants will be monitored daily (Monday – Friday) when using the updated software algorithm. The individual benefit for the participants is potentially a better regulation of their diabetes. The benefit of the study is the opportunity to implement the software update in the AP5 and future AP models to improve the diabetes management of AP users. In conclusion, burden for the participants is low and the risks associated with this study are classified as low risk. The potential benefits outweigh the risks.

We expect that the updated software algorithm will be a good successor of the current software algorithm, with potential benefits in glycemic outcome parameters and user experience. In our opinion, the burden for the participants is acceptable.

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Trial sites

Trial sites in the Netherlands

Ziekenhuis Groep Twente (ZGT)
Target size: 24

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)
Adults (18-64 years)

Inclusion criteria

- Diagnosed with diabetes mellitus type 1
- Treated with the Inreda AP system for a minimum of 1 month
- Age between 18 and 75 years
- Willing and able to sign informed consent

Exclusion criteria

- Pregnancy and/or breastfeeding
- Use of oral antidiabetic agents
- Pheochromocytoma
- Insulinoma
- Severe liver/heart/renal failure
- Alcohol abuse

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Crossover
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-06-2025
Enrollment:	24
Duration:	4 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	Medical device
Generic name:	Inreda AP
Registration:	Yes - CE intended use

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO Date:	18-06-2025
Application type:	First submission
Review commission:	MEC-U

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
Research portal	NL-009465