Fully Automated glycemic control with ultrarapid insulin in a bihormonal closed loop System in patients with Type 1 diabetes.

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The main objective is to determine the efficacy of Lyumjev in the Inreda AP system. Secondary objectives are: to assess safety, differences in pharmacodynamics and differences in AP-related outcome measures.

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

Summary

ID

NL-OMON51782

Source
ToetsingOnline

Brief title
FAST 1

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Type 1 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Inreda Diabetic B.V.

Source(s) of monetary or material Support: Bedrijf: Inreda Diabetic B.V.

Intervention

Keyword: Artificial pancreas, Diabetes, Insulin, Ultrarapid

Outcome measures

Primary outcome

Main parameter to express efficacy is the time above range (>10 mmol/l), which

will be compared between Lyumjev and Humalog.

Secondary outcome

Safety parameters

- Side effects of Lyumjev

Pharmacodynamic parameters

- Percentage of time spent in range (3.9-10.0 mmol/l)

- Percentage of time spent below range (< 3.9 mmol/l)

- Percentage of time spent in level 2 below range (< 3.0 mmol/l)

- Percentage of time spent in level 2 above range (> 13.9 mmol/l)

- Mean/median glucose value

- Glycemic variability expressed as coefficient of variation (CV) and

interquartile range (IQR)

AP-related parameters

- Daily administered dosage of glucagon

- Daily administered dosage of insulin

- The percentage of time that the closed loop algorithm is active

Study description

Background summary

Inreda Diabetic B.V. (Goor, The Netherlands) developed a bihormonal reactive closed loop system to automate glucose regulation (artificial pancreas; AP) in patients with diabetes mellitus. In the current CE-marked AP, Humalog (Eli Lilly) is used as insulin which is a rapid acting insulin lispro. Lyumjev (Eli Lilly) also consists of insulin lispro but is ultra-rapid acting due to the addition of 2 excipients. Therefore, Lyumjev is faster acting compared to Humalog. Using Lyumjev instead of Humalog insulin could therefore result in better glycemic control.

Study objective

The main objective is to determine the efficacy of Lyumjev in the Inreda AP system. Secondary objectives are: to assess safety, differences in pharmacodynamics and differences in AP-related outcome measures.

Study design

This study is a multicenter, open-labeled, randomized, cross-over trial.

Intervention

The intervention entails use of Lyumjev administered by the Inreda AP system. The subjects will be randomized to receive either Lyumjev or Humalog during the first study period of thirty days. After a wash-out period of eight days, the subject will be switched to the alternate treatment according to randomization. During both study periods subjects are asked to keep a WiFi access point with them.

Study burden and risks

There are no major risks associated with this study, since the subjects will use their usual kind of diabetes therapy, in which only the type of insulin is adjusted for thirty days. The most prominent risk is potential altered effectiveness of Lyumjev compared to the currently used insulin, which could lead to hypo- and hyperglycemia, but high and low glucose values will be indicated by alarms given by the Inreda AP system. The burden of the study is relatively low. Subjects are not required to visit the CRC and the only

additional burden for participants is to keep a WiFi access point with them during both study periods.

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

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

Exclusion criteria

- Impaired awareness of hypoglycemia (score >= 4) according to the Gold and/or Clarke questionnaire
- Pregnancy and/or breastfeeding
- Use of oral antidiabetic agents
- Insulinoma
- Hypersensitivity reactions to Lyumjev insulin or any of the excipients

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2022
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Artificial Pancreas
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Humalog
Generic name:	Insulin lispro
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Lyumjev
Generic name:	Insulin lispro
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-05-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-07-2022
Application type:	First submission
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
EudraCT	EUCTR2022-001373-31-NL
CCMO	NL79588.091.22

Study results

Date completed:	16-03-2023

Actual enrolment:	12