Dual hormone closed loop in type 1 diabetes: a randomized trial

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To determine the long-term clinical effectiveness of treatment with a dual-hormone (insulin and glucagon) fully closed loop system during 12 months compared to the current most used care and to the currently most advanced technological care....

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

Summary

ID

NL-OMON53897

Source
ToetsingOnline

Brief title
DARE

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, type 1

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Zorginstituut Nederland

Intervention

Keyword: diabetes type 1, dual hormone, fully closed loop, pump

Outcome measures

Primary outcome

The main study endpoint is the Time in Range (TIR; % of time spent in the 3.9-10 mmol/l target range) at 12 months, which will be compared between the intervention and the control treatment within each arm.

Secondary outcome

Secondary endpoints include cost-effectiveness, PROMs, other glycaemic outcomes, safety measures and device-related outcomes.

Study description

Background summary

Patients with type 1 diabetes mellitus (T1DM) require lifelong insulin therapy. Insulin therapy improves but does not fully normalise blood glucose levels with current therapies. Current therapies include subcutaneous insulin injection or subcutaneous insulin infusion, combined with a device to measure glucose levels (finger stick, intermittent sensor or continuous glucose monitoring). Although having provided a huge improvement in glycaemic control, patients have to work hard every day and still have to calculate mealtime boluses. An automated insulin delivery device covering both basal and prandial insulin requirement would mean another great leap forwards. The dual-hormone fully closed loop (DHFCL) provides a new strategy of automated insulin delivery (coupled with targeted glucagon infusion as insulin-antagonist to even more approximate normal physiology).

Study objective

To determine the long-term clinical effectiveness of treatment with a dual-hormone (insulin and glucagon) fully closed loop system during 12 months compared to the current most used care and to the currently most advanced technological care. Secondary objectives include the assessment of cost-effectiveness, Patient Reported Outcome Measures (PROMs), other glycaemic

outcomes and safety.

Study design

A 12 month open-label, two-arm randomised parallel-group trial.

Intervention

1 group will use the dual hormone fully closed loop (Inreda Diabetic; CE marked). The other group will continue their regular treatment.

Study burden and risks

There are no major risks associated with this study. The most prominent risk is failure of the closed loop to regulate the plasma glucose concentration properly, which can result in hypo- or hyperglycaemia. However, with multiple risk control measures the risk for the patients is minimized. The dual hormone fully closed loop (DHFCL) has several benefits for patients compared to current therapies. Clinical studies have shown that the DHFCL system provides better glycaemic control than insulin pump therapy, resulting in a higher percentage TIR. The DHFCL system completely takes over the glucose regulation, thereby relieving patients with regard to counting carbohydrates, estimating the amount of insulin to be administered, and taking into account future activities for glucose control.

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

• Age between 18 and 75 years;
• Diagnosed with type 1 diabetes mellitus at least one year ago;
• HbA1c <= 91 mmol/mol;

Exclusion criteria

• Current use of non-approved hybrid closed loop device;
• BMI >35 kg/m2;
• eGFR<30 mL/min/1.73m2;
• Plan to change usual diabetes regimen in the next 3 months;

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-10-2023
Enrollment:	240
Type:	Actual

Medical products/devices used

Generic name:	artificial pancreas
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-07-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	04-01-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-06-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-10-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-06-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NL81500.041.23