Efficacy and Safety of Continuous Subcutaneous Insulin Infusion of Faster-acting Insulin Aspart compared to NovoRapid® in Adults with Type 1 Diabetes.

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To confirm the effect of continious subcutaneous insulin infusion (CSII treatment) with faster-acting insulin aspart in terms of glycaemic control by comparing it to CSII treatment with NovoRapid®, in adults with Type 1 diabetes Mellitus, using a...

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

Summary

ID

NL-OMON43891

Source
ToetsingOnline

Brief title
onset® 5

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes type 1

Research involving
Human

Sponsors and support

Primary sponsor: Novo Nordisk
Source(s) of monetary or material Support: Novo Nordisk

Intervention

Keyword: Adults, Diabetes type 1, Faster acting insulin aspart, Insulin pump

Outcome measures

Primary outcome

Change from baseline in HbA1c 16 weeks after randomisation.

Secondary outcome

The confirmatory secondary endpoints are:

* Change from baseline in 1-hour PPG increment 16 weeks after randomisation

(meal test)

* Change from baseline in 1,5 anhydroglucitol 16 weeks after randomisation

* Change from baseline of time spent in low IG (*3.9 mmol/L [70 mg/dL]) during

CGM 16 weeks after randomisation.

Study description

Background summary

Data from the Diabetes Control and Complication Trial (DCCT) and UK Prospective Diabetes Study (UKPDS) shows that improvement in long term glucose control, as obtained with intensified insulin therapy, can reduce the incidence of complications and delay the progression of existing complications in Type 1 Diabetes Mellitus (T1DM) and Type 2 Diabetes Mellitus (T2DM). Control of postprandial hyperglycaemia significantly contributes to the glycosylated haemoglobin (HbA1c) level, and its treatment is essential for achieving the HbA1c target level. Basal-bolus insulin therapy aims at approaching the physiological insulin secretion profile in the healthy state to the largest possible extent. For that purpose, faster-acting insulin analogues have been developed to more effectively control the postprandial glucose (PPG) excursions

as compared to subcutaneously (s.c.) injected regular human insulin, primarily through offering a faster onset of action and shorter duration of action. However, unmet needs exist within faster-acting insulin therapy. The current insulin analogues are not able to match the speed of the physiological post-meal insulin secretion, and a faster onset of action is preferred for tighter PPG control. In addition, a more rapid delivery of the exogenous insulin to meet postprandial needs is likely to offer increased convenience and dosing flexibility for the patient.

Study objective

To confirm the effect of continious subcutaneous insulin infusion (CSII treatment) with faster-acting insulin aspart in terms of glycaemic control by comparing it to CSII treatment with NovoRapid®, in adults with Type 1 diabetes Mellitus, using a non-inferiority approach.

Study design

This is a double-blind, randomised, multicentre, multinational, active controlled, treat-to-target, parallel group trial with a 4-week run-in and a 16-week treatment period comparing the effect and safety of CSII of faster-acting insulin aspart vs. NovoRapid® in adult Subjects with T1DM. Subjects entering the trial will stay on their own insulin pump.
The duration of the trial is approximately 26 weeks split into the following periods:
* 2 weeks for screening period
a 4 week run-in primarily for reinforcement of subject training in trial procedures, diabetes education and collecting baseline assessments
a 16 week double-blinded treatment period
a 7-day follow up and 30-day safety follow-up period.
50% of the enrolled subjects is allowed to wear their own real-time CGM device during the entire course of the trial. The remaining enrolled subjects will not be allowed to wear a CGM device except for three pre-specified periods. Randomisation will be stratified for the use of own real-time CGM.

Intervention

During the run-in period the subjects will continue their current insulin treatment. At visit 6 the subjects will be randomised 1:1 to blinded NovoRapid® or faster-acting insulin aspart. After the 16 weeks of treatment subjects will switch to commercial available insulin.

Study burden and risks

Subjects are requested to visit the trial site and attend telephone calls more often than during regular treatment and several assessments are part of

standard diabetes care, but the frequency in the trial is higher.
The personal benefit for the subjects are related to the medical examination and the benefit from an intensified insulin treatment.
The anticipated risks include hypoglycaemia. hyperglycaemia, infusion site reactions, CGM related inconvenience, system allergic reactions and antibody development. Therefor the subject is closely followed during the whole trial.
Part of these risks are also seen in normal diabetescare.
See section 18.2 of the protocol.

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

Male or female, age * 18 years, at the time of signing informed consent
Type 1 diabetes mellitus * 1 year prior to the day of screening

Using the same Medtronic pump (Minimed 530G, Paradigm Veo, Paradigm Revel, Paradigm) with CSII(continuous subcutaneous insulin infusion) in a basal-bolus regimen for at least 6 months prior to screening and willing to stay on the same pump throughout the trial
HbA1c 7.0-9.0%, as assessed by central laboratory at screening
BMI*35.0 kg/m2 at screening
Ability and willigness to take at least 3 daily meal-time insulin bolus infusions every day througout the trial.

Exclusion criteria

Any of the following; myocardial infarction, stroke, hospitalisation for unstable angina or transient ischaemic attack within the past 180 days prior to the day of screening
Planned coronary, carotid or peripheral artery revascularisation known on the day of screening
History of hospitalisation for ketoacidosis *180 days prior to the day of screening
Treatment with any medication for the indication of diabetes or obesity other than stated in the inclusion criteria in a period of 90 days before screening
Any condition which, in the opinion of the Investigator. might jeopardise a Subject's safety or compliance with the protocol.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2016
Enrollment:	35

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Nog onbekend
Generic name:	Faster acting insulin Aspart
Product type:	Medicine
Brand name:	NovoRapid
Generic name:	Insulin Aspart
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-03-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-05-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-09-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2010-024054-11-NL
CCMO	NL54555.018.16