Efficacy and safety of semaglutide once weekly versus insulin glargine once daily as add on to metformin with or without sulphonylurea in insulin-naïve subjects with type 2 diabetes

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To compare the effect of once-weekly dosing of two dose levels of semaglutide versus insulin glargine once-daily on glycaemic control after 30 weeks of treatment in insulin-naïve subjects with type 2 diabetes.

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

Summary

ID

NL-OMON41148

Source
ToetsingOnline

Brief title
SUSTAIN* 4 * vs. Basal Insulin

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, diabetes mellitus type 2

Research involving
Human

Sponsors and support

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

Intervention

Keyword: GLP-1 analogue, semaglutide, type 2 diabetes

Outcome measures

Primary outcome

Change from baseline to week 30 in HbA1c.

Secondary outcome

Change from baseline to week 30 in:

* body weight

* Fasting plasma glucose (FPG)

* Systolic and diastolic blood pressure

* Patient reported outcome questionnaires (PROs)

Subjects who after 30 weeks treatment achieve (yes/no):

* HbA1c *6.5% (48 mmol/mol) American Association of Clinical Endocrinologists

(AACE) target

Study description

Background summary

The currently available treatment modalities for type 2 diabetes are still not satisfactory and there is a large proportion of patients not reaching the treatment targets despite high level of compliance with the treatment regimens. Furthermore, there is a segment of patients where either compliance with once-daily treatment regimens is an issue resulting in sub-optimal glycaemic

control, or where there is a wish for a more convenient treatment regimen. Therefore, development of once-weekly GLP-1 analogues have the potential to fulfil a medical need.

Study objective

To compare the effect of once-weekly dosing of two dose levels of semaglutide versus insulin glargine once-daily on glycaemic control after 30 weeks of treatment in insulin-naïve subjects with type 2 diabetes.

Study design

This is a 30-week randomised, open-label, active-controlled, parallel-group, multicentre, multi-national, three-armed trial comparing two doses of semaglutide (0,5 mg and 1,0 mg) once-weekly versus insulin glargine once-daily. Insulin-naïve subjects with type 2 diabetes inadequately controlled with metformin or metformin and sulphonylurea (SU) will after a 2 weeks screening period be randomised in a 1:1:1 manner to receive either a dose of 0.5 mg or 1.0 mg of semaglutide once weekly or insulin glargine once daily treated to target (T-T-T).
The treatment period is 30 weeks in total and is followed by a follow-up visit after 5 weeks. Total trial duration for the individual subjects will be up to 37 weeks.

Intervention

Self-injection of semaglutide 0,5 mg or 1.0 mg once-weekly or insuline glargine once-daily.

Study burden and risks

Subjects will have to visit the clinic more often for the trial. They will get more venapunctures and will be asked to perform blood glucose measurements. There is also a risk of side effects.
It is concluded that the potential benefits from participating in the trial outweigh the potential risks. The safety profile of semaglutide generated from the clinical and non-clinical development programme has not revealed any safety issues that would prohibit administration of once weekly doses of 0.5 mg or 1.0 mg semaglutide in accordance with the planned clinical trial. It is concluded that the risk to the subjects in this trial is low and acceptable in view of the benefits a long-acting GLP-1 analogue would provide to people with type 2 diabetes.
IGlar is approved for treatment of type 2 diabetes in several countries including US and EU and it is concluded that the risk to the subjects treated with IGlar in this trial is low.

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. Male or female, age *18 years at the time of signing informed consent;2. Insulin-naïve subjects diagnosed with type 2 diabetes and on stable diabetes treatment with metformin or metformin and SU (metformin *1500 mg or maximum tolerated dose and SU * half of maximum allowed dose according to national label) for at least 90 days before screening. Stable is defined as unchanged medication and unchanged dose;3. HbA1c 7.0 * 10.0% (53 - 86 mmol/mol) both inclusive

Exclusion criteria

1. Female who is pregnant, breast-feeding or intends to become pregnant or of childbearing potential not using adequate contraceptive method (adequate contraceptive measures as

required by local regulation or practice) throughout the trial including the 5 week follow-up period;2. Any disorder which, in the opinion of the Investigator might jeopardise subject*s safety or compliance with the protocol;3. Treatment with any glucose lowering agent(s) other than stated in the inclusion criteria in a period of 90 days before screening. An exception is short-term treatment (*7 days in total) with insulin in connection with intercurrent illness;4. History of chronic or idiopathic acute pancreatitis;5. Screening calcitonin value *50 ng/L;6. Personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome 2;7. Severe renal impairment defined as eGFR <30 mL/min/1.73 m^2 per modification of diet in renal disease (MDRD) formula (4 variable version);8. Acute coronary or cerebrovascular event within 90 days before randomisation;9. Heart failure, New York Heart Association Class IV;10. Known proliferative retinopathy or maculopathy requiring acute treatment according to the opinion of the investigator;11. Diagnosis of malignant neoplasm in the previous 5 years (except basal cell skin cancer or squamous cell skin cancer)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2014
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lantus
Generic name:	Insulin glargine

Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Not yet known
Generic name:	semaglutide

Ethics review

Approved WMO Date:	27-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2014
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	EUCTR2013-004392-12-NL
ClinicalTrials.gov	NCT02128932
CCMO	NL47781.018.14