Efficacy and safety of semaglutide once-weekly versus exenatide ER 2.0 mg once-weekly as add-on to 1-2 oral antidiabetic drugs (OADs) in subjects with type 2 diabetes.

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To compare the effect of semaglutide 1.0 mg once-weekly versus exenatide extended release (ER) 2.0 mg once-weekly on glycaemic control after 56 weeks of treatment.

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

Summary

ID

NL-OMON40243

Source
ToetsingOnline

Brief title
SUSTAIN 3 - vs. QW GLP-1

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 56 in HbA1c.

Secondary outcome

*Change from baseline to week 56 in body weight

*Change from baseline to week 56 in: Fasting Plasma Glucose (FPG), Systolic and diastolic blood pressure, Patient reported outcome (PRO) questionnaire Diabetes Treatment Satisfaction Questionnaire status (DTSQs)

*Subjects who after 56 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 semaglutide 1.0 mg once-weekly versus exenatide extended release (ER) 2.0 mg once-weekly on glycaemic control after 56 weeks of treatment.

Study design

This is a 56-weeks randomised, open-label, active-controlled parallel-group, multi-national, multicentre trial. Subjects will be randomised in a 1:1 manner to receive a dose of 1.0 mg semaglutide once-weekly or exenatide ER 2.0 mg once-weekly. Trial product will be add-on to the subject*s pre-trial medication consisting of 1-2 of the following compounds: metformin, sulfonylureas (SU) or thiazolidinediones (TZDs).

Intervention

Self-injection of semaglutide 1.0 mg once-weekly or exenatide ER 2.0 mg once-weekly.

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 these potential risks. The safety profile of semaglutide generated from the clinical and nonclinical development programme has not revealed any safety issues that would prohibit administration of once weekly doses of 1.0 mg semaglutide in accordance with the planned clinical trial. Exenatide ER is already a marketed drug in the 2 mg dose and approved for the use in type 2 diabetic patients. 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 subjects with type 2 diabetes.

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.
*Subjects diagnosed with type 2 diabetes and on stable diabetes treatment with 1-2 OADs (Metformin * 1500 mg or maximum tolerated dose and/or TZD and/or SUs * half of maximum dose allowed according to national label) for at least 90 days prior to screening. Stable is defined as unchanged medication and unchanged dose
*HbA1c 7.0 * 10.5 % (53 * 91 mmol/mol) (both inclusive)

Exclusion criteria

*Females of childbearing potential who are pregnant, breast-feeding or intend to become pregnant or are not using an adequate contraceptive method throughout the trial including the 5 weeks follow-up period (adequate contraceptive measures as required by local law or practice)
*Any chronic disorder or severe disease which, in the opinion of the investigator, might jeopardise subject*s safety or compliance with the protocol
Treatment with 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 inter-current illness
*History of chronic or idiopathic acute pancreatitis
*Screening calcitonin value * 50 ng/L (pg/mL)
*Personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2)
*Impaired renal function defined as eGFR < 60 ml/min/1.73 m2 per modification of diet in

renal disease (MDRD) formula (4 variable version)
*Acute coronary or cerebrovascular event within 90 days before randomisation
*Heart failure, New York Heart Association (NYHA) class IV

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):	23-01-2014
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bydureon
Generic name:	exenatide ER
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	semaglutide
Generic name:	semaglutide

Ethics review

Approved WMO
Date: 08-08-2013

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 10-12-2013

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 21-02-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 27-02-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 13-03-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 28-03-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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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	EUCTR2012-004826-92-NL
CCMO	NL44815.098.13