The effect of liraglutide versus placebo when added to basal insulin analogues with or without metformin in subjects with type 2 diabetes
A 26-week double-blind placebo-controlled randomised multicentre, multinational parallel-group trial

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To confirm superiority on glycaemic control of liraglutide versus placebo after 26 weeks of treatment when added to pre-existing basal insulin analogue treatment (with or without concomitant metformin treatment) in 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-OMON37485

Source
ToetsingOnline

Brief title
NN2211-3917

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, diabetes mellitus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: diabetes mellitus, liraglutide

Outcome measures

Primary outcome

Change in HbA1c from baseline to week 26.

Secondary outcome

Change from baseline to week 26 in:

• Fasting plasma glucose (FPG).

• 7-point self-measured plasma glucose

• Body weight

After 26 weeks treatment:

Number of subjects achieving:

• HbA1c < 7.0% (American Diabetes Association (ADA) target).

• HbA1c <= 6.5% (American Association of Clinical Endocrinologists (AACE)

target)

Safety (after 26 weeks of treatment)

Number of subjects with:

• Adverse events (AEs)

• Minor or severe hypoglycaemic episodes

Study description

Background summary

The progressive nature of type 2 diabetes combined with its increasing prevalence and the fact that patients are being diagnosed at a progressively younger age, mean that an increasing number of patients require insulin therapy to maintain glycaemic control.
Liraglutide has proven to be a well-tolerated and efficacious treatment option in a wide variety of subjects with type 2 diabetes when added to OADs. Treatment with liraglutide leads to substantial and clinically relevant lowering of HbA1c and reductions in body weight without increased risk of hypoglycaemic episodes due to the glucose dependent mode-of-action. These effects indicate that liraglutide may be a valuable complementary treatment option in type 2 diabetic patients insufficiently controlled on insulin therapy. Currently, liraglutide is not approved for use in combination with insulin. However, results from a recent phase 3b trial have shown that intensification of treatment with insulin detemir in subjects with type 2 diabetes not achieving adequate glycaemic control with liraglutide + metformin was well-tolerated and efficacious.
Studies indicate that addition of a GLP-1 receptor agonist to pre-existing insulin therapy can favourably affect the daily glucose variability by reducing plasma glucose excursions and provide improved glycaemic control with significant reductions in HbA1c. These effects of the combination therapy seemed associated with a reduced need for insulin, weight loss and no substantial increase in the risk of hypoglycaemic events. The efficacy and safety of liraglutide as add on to basal insulin analogues has however, never been established in a controlled, double blind setting.

Study objective

To confirm superiority on glycaemic control of liraglutide versus placebo after 26 weeks of treatment when added to pre-existing basal insulin analogue treatment (with or without concomitant metformin treatment) in subjects with type 2 diabetes.

Study design

The trial is a 26 week, randomised, double-blind, placebo-controlled two-armed, parallel group, multi-centre, multi-national trial.
Subjects will be randomised in a 1:1 manner to receive a once daily dose of

liraglutide 1.8 mg or liraglutide placebo.

Intervention

Participants will inject themselves with Liraglutide, 6.0 mg/mL or liraglutide placebo

Study burden and risks

Patients will have to visit the clinic more often for the trial. They will get more venapunctures and will be asked to perform home blood glucose measurements. Liraglutide is already a marketed product. Patient could experience side effects from using liraglutide.

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 2 diabetes for at least 180 days prior to screening
-HbA1c 7.0-10.0% (both inclusive)
-Body mass index (BMI) 20.0-45.0 kg/m2 (both inclusive)
-Age 18-80 years (both inclusive)

Exclusion criteria

•Female who is pregnant, breast-feeding or intend to become pregnant
•Recurrent severe hypoglycaemic episodes or hypoglycaemic unawareness
•Treatment with glucose-lowering agent(s) other than stated in the inclusion criteria in a period of 12 weeks prior to screening
•Impaired liver or renal function
•Uncontrolled treated or untreated hypertension (SBP >=180 mmHg and/or DBP >=100 mmHg)
•Any clinically significant disorder, except for conditions associated with type 2 diabetes history which in the investigator*s opinion could interfere with results of the trial
•Known or suspected abuse of alcohol or narcotics

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2012
Enrollment:	30

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Victoza
Generic name:	Liraglutide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	04-06-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	24-07-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	23-08-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-11-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-11-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	

Date:	14-06-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2011-002696-41-NL
CCMO	NL40373.075.12