6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® Both plus Mealtime Insulin in Patients with Type 2 Diabetes Mellitus with a 6-month Safety Extension Period

Published: 19-08-2011
Last updated: 28-04-2024

The purpose of the multicenter, randomized, open-label, parallel-group study EFC11628 is to compare the efficacy and safety of HOE901-U300 with that of Lantus®, both given once-daily s.c. as part of a basal-bolus insulin regimen in patients with...

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

Summary

ID

NL-OMON39048

Source
ToetsingOnline

Brief title
EDITION I

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes Mellitus type 2

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis
Source(s) of monetary or material Support: door verrichter

Intervention

Keyword: Diabetes type 2, HOE901-U300

Outcome measures

Primary outcome

Efficacy:

HbA1c [change from baseline to endpoint (week 24)]

Secondary outcome

Main secondary endpoints:

• Incidence of patients (%) with at least one nocturnal hypoglycemia between start of week 9 and endpoint (month 6), indicated as severe and/or confirmed by plasma glucose < or = 3.9 mmol/L.

• Change in preinjection plasma glucose from baseline to endpoint (month 6)

• Change in variability of preinjection plasma glucose from baseline to endpoint (month 6)

Other secondary endpoints:

responder analyses for HbA1c and FPG (fasting plasma glucose), and changes from baseline to endpoint in FPG, 24-hour mean plasma glucose, variability of plasma glucose, daily basal insulin dose, daily total insulin dose and free fatty acids.

Safety/Tolerability:

Safety and tolerability analyses will include hypoglycemia, adverse events,

serious adverse events, physical examination, vital signs,

hematology, serum chemistry (see protocol page 12,13 and 14), lipids, ECG,

anti-insulin antibodies, injection site reactions.

Patient reported outcome (PRO):

Diabetes Treatment Satisfaction Questionnaire (DTSQs), Perceived Hyperglycemia

and Perceived Hypoglycemia.

Study description

Background summary

Insulin glargine U100 has been marketed as Lantus for more than 10 years. Its efficacy and safety are well-known through extensive data collection involving over 100 000 patients in clinical studies, including randomized, controlled clinical trials and the results of post-marketing surveillance.
The development of HOE901-U300, a concentrated formulation of insulin glargine, was initiated based on the observation that daily basal insulin dose requirements increase, when patients are treated to achieve and maintain glycemic control, resulting in inconvenient, large volume subcutaneous injections. HOE901-U300 has the same composition as the current Lantus formulation 100 U/mL with adjustment of 3-times the amount of active pharmaceutical ingredient and corresponding Zn content.

Study objective

The purpose of the multicenter, randomized, open-label, parallel-group study EFC11628 is to compare the efficacy and safety of HOE901-U300 with that of Lantus®, both given once-daily s.c. as part of a basal-bolus insulin regimen in patients with type 2 diabetes.

The objective of the pharmacogenetic substudy is to investigate the influence of DNA differences on how the body responds to and how the body handles Lantus

and the new formulation of insulin glargine HOE901-U300.

Study design

Randomized, open-label, 2-arm parallel-group multicenter trial. Patients will receive in a 1:1 ratio either HOE901-U300 or Lantus®.
The study will include an up to 2-week screening period, a 24-week efficacy and safety period and a 12-month safety extension period.

Intervention

One group receives HOE901-U300 as basal insulin and the other group receives Lantus® (insulin glargine) as basal insulin.

Study burden and risks

The risks are related to the blood sampling and possible side effect of the study medication. The burden for the patient consists of planned number of visits and telephone calls needed for this trial. The patients will be asked to keep the e-diary up to date and to performs self measured bloodglucose measurements.

From patients who are willing to participate in the pharmacogentic substudy a separate blood sample will be collected (approximately 6 mL).
If possible, the blood sampling will be performed in conjunction with blood sampling for the main clinical trial EFC11628.

Contacts

Public
Sanofi-aventis

Kampenringweg 45E
GOUDA 2803 PE
NL
Scientific
Sanofi-aventis

Kampenringweg 45E
GOUDA 2803 PE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with type 2 diabetes mellitus

Exclusion criteria

- Age <18 years;
- HbA1c < 7.0% or >10% at screening;
- Diabetes other than type 2 diabetes mellitus;
- Less than 1 year on basal plus mealtime insulin and self-monitoring of blood glucose;
- Patients using pre-mix insulins or basal insulins other than insulin glargine or NPH and patients using any non-insulin antihyperglycemic drugs other than metformin in the last 3 months before screening;
- Any contraindication to use of insulin glargine as defined in the national product label;
- Patients using human regular insulin as mealtime insulin in the last 3 months before screening visit;
- Use of an insulin pump in the last 6 months before screening visit;
- Initiation of new glucose-lowering agents and/or weight loss drugs in the last 3 months before
screening visit;
- History or presence of clinical significant macular edema likely to require treatment during the study period;
- Most recent eye examination by an opthalmologist>12 months prior randomization visit
- Pregnant or breast-feeding women or women who intend to become pregnant during the study period.
- Patient who has taken other investigational drugs within 1 month or 5 half-lives, whichever is longer

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):	15-02-2012
Enrollment:	40
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:	niet van toepassing
Generic name:	insulin glargine U300

Ethics review

Approved WMO

Date:	19-08-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	30-09-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-08-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-09-2012
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-06-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-06-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2010-023769-23-NL
ClinicalTrials.gov	NCT01499082
CCMO	NL37496.060.11