A 52-WEEK MULTICENTER, OPEN-LABEL, RANDOMIZED, PARALLEL, TWO - ARM STUDY COMPARING EXUBERA® (INHALED HUMAN INSULIN) VS. HUMALOG® (INSULIN LISPRO), BOTH IN COMBINATION WITH INSULIN GLARGINE IN SUBJECTS WITH TYPE 1 DIABETES MELLITUS

Published: 11-01-2007
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Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON30738

Source
ToetsingOnline

Brief title
Exist

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
?, Diabetes Mellitus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diabetes mellitus type I, Exubera®, Humalog®, Inhaled human insulin

Outcome measures

Primary outcome

The primary efficacy endpoint is the change from baseline to week 52 in HbA1c

(%).

Secondary outcome

1. Hypoglycemic event rates during the entire study

2. Percentage of subjects who obtained an HbA1c < 8 %,< 7%, <6.5%, and > 8% at

52 weeks.

3. Percentage of subjects with >0.5, >0.7 and >1.0% absolute reduction in HbA1c

levels at 52 weeks from baseline levels.

4. Percentage of subjects who attain target FPG values 4.0 * 6.5 mmol/l at each

evaluation from baseline to 52 weeks.

5. Change in fasting plasma glucose from baseline to endpoint and change in fasting and post-prandial blood glucose from baseline to 52 weeks based on glucometer data and in-hospital assessments.

6. Change in insulin antibody levels and body weight from baseline to 52 weeks.

7. Change in body weight and body mass index from baseline to 52 weeks.

8. Change in basal and prandial insulin doses from baseline to 52 weeks.

9. Blood glucose values determined by home-monitored blood glucose (HMBG) from baseline to 52 weeks.

10. Subject reported health state, quality of life (as measured by physical, physiological and work and daily role functioning) and diabetes treatment satisfaction from baseline to 52 weeks.

11. Change in fasting lipids from baseline to 52 weeks.

Study description

Background summary

The new way of administration with Exubera® makes it possible for diabetes patients to treat themselves in a non-invasive way. This study should show that the glycemic controle after 52 weeks of treatment of Exubera® given in combination with Lantus® is not inferior comared to Humalog® in combination

with Lantus®.

Study objective

The primary objective of the study is to demonstrate non-inferiority of an insulin regimen using insulin glargine as the basal insulin with Exubera as the mealtime insulin, compared to a regimen using insulin glargine as the basal insulin and insulin lispro as the mealtime insulin in terms of glycemic control (HbA1c) after 52 weeks of treatment with each treatment regimen.

Study design

This is a randomized open-label, parallel-group outpatient and inpatient study with a 4-week run-in period, and a 52-week treatment period. Half of the subjects will receive an inhaled insulin regimen and half a subcutaneous insulin regimen. All subjects will receive insulin glargine as basal regimen.

This study contains three sub-studies that are outlined in Appendices 4, 5 and 6 of the protocol.

Intervention

Patients will be randomised to one of the two treatment groups, being: Humalog and Lantus or Exubera and Lantus.

Study burden and risks

Patients visit a dietician at week -3. Patients will have to perform home blood glusoce monitoring by means of a bloodglucose meter.
This is part of the dialy routine for diabetes patients. Although for the study more measurements need to be done.

During the study questionnaires need to be completed, 7 times.

A brief physical examination will be performed 14 times during the study.

A spirometry will be performed at least once. For patients randomised on Exubera this will be done three times (in total).

Patients are expected to follow the studyprocedures as described in the protocol during the duration of the study.

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. Subjects with type 1 diabetes mellitus
2. Age: > 18 years
3. For the 2 months prior to screening, subjects must have been on a stable insulin regimen involving at least 3 injections daily of insulin or an insulin analogue
4. Screening (week-4) HbA1c between 5.5% and 9.0% inclusive
5. Body Mass Index * 30
6. The investigator will be responsible for obtaining written informed consent prior to the subject participating in the study

Exclusion criteria

1. Pregnant or lactating females, or females planning to become pregnant during the study
2. Subjects on insulin pump treatment as part of their MDI regime during the 2 months prior to screening
3. Subjects with *brittle* diabetes or a predisposition to severe hypoglycemia
4. Some pulmonary, cardiovascular, neurological, phychological and metabolic conditions (see page 17/18 of the protocol)
5. Concomitant therapy with systemic glucocorticoids

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2007
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Exubera®
Generic name:	Inhaled human insulin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Humalog®
Generic name:	Insulin Lispro

Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Lantus®
Generic name:	Insulin glargine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	11-01-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-01-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-01-2008
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-05-2008
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	EUCTR2004-001557-29-NL
CCMO	NL13503.018.06