Exenatide-study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26218

Source
NTR

Brief title
Exenatide-study

Health condition

Type 2 Diabetes Mellitus.

Sponsors and support

Primary sponsor: Eli Lilly and Company, Lilly Nederland BV
Source(s) of monetary or material Support: Eli Lilly and Company, Lilly Nederland BV

Intervention

Outcome measures

Primary outcome

Glycaemic control and beta-cell function, measured at baseline and after 52 weeks of exenatide or insulin glargine administration.

Secondary outcome

1. Postprandial blood glucose, lipids, lipoproteins and markers of inflammation, coagulation, endothelial function;

2. Proportion of subjects with baseline HbA1c >7.0% that achieve HbA1c £7.0%. Proportion of subjects with baseline HbA1c >6.5% that achieve HbA1c £6.5%;

3. Seven-point self-monitored blood glucose profiles.

Study description

Background summary

A Phase 3, randomised, open-label, comparator-controlled, parallel-group, multicenter, study is comparing the effects of exenatide and insulin glargine on beta-cell function in subjects with type 2 diabetes mellitus who have not achieved target HbA1c (£7.0%) using metformin therapy.
75 insulin-naive subjects (25 per research center and approximately 37 per treatment group) will be studied.
Subjects will be males or females, 30 to 70 years of age, with a BMI ³25 kg/m2 and £40 kg/m2 at screening.
Subjects must have a HbA1c between 6.6% and 9.5%, inclusive.

Study objective

Exenatide improves first and second phase insuline secretion compared to insulin glargine.

Study design

N/A

Intervention

Randomisation in 2 arms (exenatide vs. insulin glargine). The duration of the intervention is 52 weeks. Exenatide and insulin glargine dose titration will be based upon HbA1c and fasting plasma glucose, respectively.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with type 2 diabetes mellitus (m/f);

2. 30-70 years of age;

3. Body mass index 25-40 kg/m2;

4. Using stable (>2 months) oral anti-diabetic therapy with metformine alone;

5. Subjects must have HbA1c between 6.6% and 9.5%, inclusive.

Exclusion criteria

1. Use of oral anti-diabetic therapy other than metformine.

2. Clinical significant history or presence of hepatic-, renal-, central nervous system-, gastrointestinal-, haematological- and pulmonary disease;

3. Blood pressure >165/95.

4. Electrocardiogram with clinically significant abnormalities as judged by the investigator;

5. The use of prohibited medication as specified in the protocol.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2004
Enrollment:	75
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005
Application type:	First submission

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
NTR-new	NL245
NTR-old	NTR283
Other	: N/A
ISRCTN	ISRCTN87762302

Study results

Summary results
N/A