

A Phase III, randomized, open-label, comparator-controlled, parallel-group, multicenter study to compare the effects of exenatide and insulin glargine on beta-cell function and cardiovascular risk markers in subjects with type 2 diabetes treated with metformin who have not achieved target HbA1c

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/12/2005	Overall study status Completed	☐ Protocol
Last Edited 11/04/2019	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00097500

Study information

Scientific Title

A Phase III, randomized, open-label, comparator-controlled, parallel-group, multicenter study to compare the effects of exenatide and insulin glargine on beta-cell function and cardiovascular risk markers in subjects with type 2 diabetes treated with metformin who have not achieved target HbA1c

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Phase III randomized open-label comparator-controlled parallel-group, multicenter

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes Mellitus type II (DM type II)

Interventions

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.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Exenatide, insulin glargine

Primary outcome(s)

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

Key secondary outcome(s)

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.

Completion date

31/12/2006

Eligibility**Key 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 metformin alone
5. Subjects must have HbA1c between 6.6% and 9.5%, inclusive.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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

Date of first enrolment

15/10/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

VU University Medical Center

Amsterdam

Netherlands

1081 HV

Sponsor information

Organisation

Eli-Lilly (The Netherlands)

ROR

<https://ror.org/02ve0bg52>

Funder(s)

Funder type

Industry

Funder Name

Eli Lilly and Company

Alternative Name(s)

Lilly, Eli Lilly & Company, Eli Lilly & Co., Eli Lilly And Co, Eli Lilly & Co

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009	21/02/2019	Yes	No
Basic results				No	No