

# 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

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/04/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00097500

Secondary identifying numbers

N/A

## 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

### Study design

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

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure**

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

**Secondary outcome measures**

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.

**Overall study start date**

15/10/2004

**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/m<sup>2</sup>
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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

3 sites: Netherlands, Sweden and Finland, 25 patients each

**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)

**Sponsor details**

Lilly Nederland BV P.O. Box 379

Houten

Netherlands

3990 GD

**Sponsor type**

Not defined

**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

## Funding Body Type

Government organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

United States of America

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>				No	No
<a href="#">Results article</a>	results	01/05/2009	21/02/2019	Yes	No