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  Overall study status Completed	Prospectively registered		
Registration date		<ul><li>Protocol</li><li>Statistical analysis plan</li></ul>		
20/12/2005		[X] Results		
<b>Last Edited</b> 11/04/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	Individual participant data		

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

## ClinicalTrials.gov (NCT)

NCT00097500

#### Protocol serial number

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

## 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

1081 HV

Study participating centre
VU University Medical Center
Amsterdam
Netherlands

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes