ISRCTN87762302 https://doi.org/10.1186/ISRCTN87762302

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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
11/04/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mathijs C.M. Bunck

Contact details
VU University Medical Center
Diabetes Center Department of Endocrinology
De Boelelaan 1117
Room L-049
Amsterdam
Netherlands
1081 HV
+31 (0)20 4442789
mcmbunck@vumc.nl

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/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

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?
Basic results				No	No
Results article	results	01/05/2009	21/02/2019	Yes	No