Pharmacokinetics and pharmacodynamics of insulin detemir (Levemir®) and insulin glargine (Lantus®) after subcutaneous injection of increasing doses into morbidly obese type 2 diabetic subjects

Submission date	Recruitment status	Prospectively registered
07/04/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
09/05/2006	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
01/02/2019	Nutritional, Metabolic, Endocrine	

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

Protocol serial number

N/A

Study information

Scientific Title

Pharmacokinetics and pharmacodynamics of insulin detemir (Levemir®) and insulin glargine (Lantus®) after subcutaneous injection of increasing doses into morbidly obese type 2 diabetic subjects

Acronym

INSULIN-KINETICS

Study objectives

The primary aim of this study is to compare the dose-response relationship of moderate and of high doses of insulin determinand of insulin glargine in severely obese type 2 diabetic subjects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Local Ethics Committee of the University of Basel (EKBB) on 16/01/2003, reference number 295/05

Study design

Randomized cross-over trial with 2 insulins (determir and glargine) and 2 dosages each

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes, obesity

Interventions

Application of insulin determir (Levemir) versus insulin glargine (Lantus)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Insulin detemir (Levemir) and insulin glargine (Lantus)

Primary outcome(s)

Pharmacodynamics of the two insulins (detemir and glargine)

Key secondary outcome(s))

- 1. Pharmacokinetics of the two insulins (detemir and glargine)
- 2. Correlation pharmacodynamics and (central) obesity

Completion date

30/04/2007

Eligibility

Key inclusion criteria

- 1. History of type 2 diabetes mellitus
- 2. Age 18-65 years
- 3. Body mass index >35 kg/m^2
- 4. HbA1c <10%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

- 1. Any severely active hepatic, cardiovascular, pulmonary, renal, neurological, musculoskeletal, hematological or endocrine disease
- 2. Pregnant or breast feeding women
- 3. Woman of childbearing potential not using a reliable method of birth control such as oral contraceptives or an intrauterine device (IUD)
- 4. Subjects refusing or unable to give written informed consent

Date of first enrolment

20/04/2006

Date of final enrolment

30/04/2007

Locations

Countries of recruitment

Study participating centre University Hospital Basel Basel Switzerland 4031

Sponsor information

Organisation

University Hospital Basel (Switzerland)

ROR

https://ror.org/04k51q396

Funder(s)

Funder type

Industry

Funder Name

Novo Nordisk AG, Switzerland

Funder Name

Foundations

Results and Publications

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?
Results article	results	16/08/2018	01/02/2019	Yes	No