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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
07/04/2006	No longer recruiting
Registration date	**Overall study status**
09/05/2006	Completed
Last Edited	**Condition category**
01/02/2019	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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 detemir and 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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Pharmacodynamics of the two insulins (detemir and glargine)

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

Overall study start date
20/04/2006

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
8-12

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
Switzerland

Study participating centre
University Hospital Basel
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital Basel (Switzerland)

Sponsor details
Division of Endocrinology, Diabetology and Clinical Nutrition
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Sponsor type
University/education

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Industry

Funder Name
Novo Nordisk AG, Switzerland

Funder Name
Foundations

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