

# 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**

07/04/2006

**Recruitment status**

No longer recruiting

**Registration date**

09/05/2006

**Overall study status**

Completed

**Last Edited**

01/02/2019

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ 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  $>35 \text{ kg/m}^2$
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?
<a href="#">Results article</a>	results	16/08/2018	01/02/2019	Yes	No