

# Detemir versus Glargine for weight gain in adolescents with type 1 diabetes

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/05/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Diabetes is a life-long condition where a person is unable to control their blood sugar levels. There are two main types of diabetes. In type 1 diabetes the body is unable to produce a hormone called insulin, which is responsible for breaking down glucose and turning it into energy. When this happens, sufferers need to inject insulin to make sure that their blood sugar levels stay normal. Most people use long-acting insulin to give a continuous low level in the blood stream and a short acting insulin to give a “boost” at meal times. There are several different types of insulin made. This study is looking at the differences between two relatively new insulins, called Detemir (or Levemir) and another one called Glargine (or Lantus). Although it is normal to gain weight with age, girls with diabetes may have more weight gain than girls without diabetes. Levemir appears to cause less weight gain than insulin (the conventional ‘cloudy’ long acting insulin) in adults and young people with diabetes, but it has never been compared with Lantus in young women. The aim of this study is to find out whether there are any differences in weight gain in young women using these different types of insulin.

### Who can participate?

Girls aged between 13 and 20 with T1DM.

### What does the study involve?

Participants who agree to take part in the study are randomly allocated to receive either Insulin Detemir (Levemir) or Insulin Glargine (Lantus). The study lasts for one year and involves six clinic visits and regular telephone and/or email contact (minimum 12) with the research nurse. At each visit the participant’s height, weight, blood pressure and waist circumference are measured. The participants are also asked to complete a brief questionnaire about appetite. During the study, participants are asked to check and record their blood sugar before breakfast, their evening meal, before bedtime, and whenever they feel as if their blood sugars are low. At two months, participants are asked to record their blood sugar values on a 5 point profile (breakfast, lunch, evening meal, bedtime and once overnight at around 0200h). In centres which have the necessary equipment, after 3 months and at the very end of the study, glucose values for three days, using a continuous glucose monitoring sensor, are recorded. The sensor is a small electrode that lies just beneath the skin and can convert tiny amounts of glucose into a signal that is sent and stored by the monitor which is downloaded into a computer file. At the

beginning and end of the study, where appropriate facilities are available, participants are asked to have a scan to measure body fat distribution. Four times throughout the study; at the beginning, end and after three and six months, blood samples are taken to assess overall glucose control over the preceding three months and levels of other hormones within the blood, such as testosterone, which may vary in young women with diabetes. Anyone can have anaesthetic (numbing) cream applied to the skin before the blood test is done if they prefer.

What are the possible benefits and risks of participating?

There are no direct benefits involved with participating. There is a small risk of pain, bruising or infection when blood samples are taken using blood tests or the continuous glucose monitoring sensor.

Where is the study run from?

Addenbrooke's Hospital and 24 other hospitals in England (UK)

When is the study starting and how long is it expected to run for?

September 2005 to January 2017

Who is funding the study?

Novo Nordisk Pharmaceuticals Limited (UK)

Who is the main contact?

Ms Diane Picton

dp223@medschl.cam.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Ms Diane Picton

### Contact details

Addenbrooke's Hospital

Department of Paediatrics

Cambridge

United Kingdom

CB2 2QQ

+44 1223 768613

dp223@medschl.cam.ac.uk

## Additional identifiers

### EudraCT/CTIS number

2007-004144-74

### IRAS number

### ClinicalTrials.gov number

## Secondary identifying numbers

4903

# Study information

## Scientific Title

A comparison of the effects of insulin Detemir with insulin Glargine on weight gain in female adolescents and young adults with type 1 diabetes on a basal bolus regime

## Acronym

DETEMIR GLARGINE

## Study objectives

The aim of this study is to explore the hypothesis that use of insulin detemir versus insulin glargine will lead to reduced weight gain in young women with T1D.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Oxfordshire REC A, 26/10/2008, ref: 07/H0604/122

## Study design

Multicentre randomised interventional treatment trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

See additional files

## Health condition(s) or problem(s) studied

Topic: Medicines for Children Research Network, Diabetes Research Network; Subtopic: Type 1, All Diagnoses; Disease: All Diseases, Insulin switch, Metabolic, Paediatric

## Interventions

Interventions as of 22/05/2017:

Eligible subjects will be randomised to one of two groups using an internet based service ([www.sealedenvelope.com](http://www.sealedenvelope.com)) with minimisation of variation in:

1. Age (< or  $\geq$  16yrs)
2. BMI SDS (< or  $\geq$  1 SDS)

3. HbA1c (< or  $\geq$  8 % or 64mmol/mol)

4. Years post menarche (< or  $\geq$  2yrs)

5. Centre

Randomisation will be 1:1 between the arms. The web based randomisation service is password protected on a secure server and no identifiable patient details will be entered. Following randomisation, a completed form, confirming treatment will be faxed back to the local research team. The local team will then notify their pharmacist in order to facilitate local dispensing prior to the participant attending for their baseline visit.

Group 1: Participants receive Levemir®. 1 ml of the solution contains 100 U insulin detemir\* (equivalent to 14.2 mg). 1 pre-filled pen contains 3 ml equivalent to 300 U

Group 2: Participants receive Lantus®. 100 units insulin Glargine (equivalent to 3.64mg). Each pen consist of 3mls of solution (equivalent to 300units)

Both insulins dosages are titrated to fasting glucose aiming for a target range of 4-8mmol/l.

Original interventions:

1. Lantus® Optiset (600 nmol/ml [100 IU/ml] in 3 ml pre-filled, disposable pen device) dosage variable/subcut/frequency once or twice day

2. Lantus® Solostar (600 nmol/ml [100 IU/ml] in 3 ml pre-filled, disposable pen device) dosage variable/subcut/frequency once or twice day

3. Levemir® FLEX-PEN (2400 nmol/ml [100 U/ml] in 3 ml pre-filled, disposable pen device) dosage variable/subcut/frequency once or twice day

Duration of treatment: one year

Duration of follow-up: No follow-up

Study entry: single randomisation only

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Determir, glargine

## **Primary outcome measure**

Reduced weight gain. Full body dual energy x-ray absorptiometry (DEXA) will be done at baseline and 1 year.

## **Secondary outcome measures**

To explore differences between the two insulins on the following:

1. HBa1c

2. Fat mass

Study bloods will be taken at baseline, 6 and 12 months.

## **Overall study start date**

01/09/2005

**Completion date**

12/01/2017

## Eligibility

**Key inclusion criteria**

1. Type 1 diabetes (T1D) duration greater than 1 year or C peptide negative
2. Females, postmenarchal, 13 - 20 years of age
3. HbA1c less than 12%
4. Body mass index (BMI) SDS less than or equal to +2.5
5. On basal bolus regime
6. No active or untreated concurrent disease

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Planned sample size: 112; UK sample size: 112

**Total final enrolment**

97

**Key exclusion criteria**

1. Non-T1D including those secondary to chronic disease
2. Any other physical or psychological disease likely to interfere with the normal conduct of the study and interpretation of the study results
3. Pregnant or breastfeeding women
4. Females of reproductive age who are unwilling to take appropriate measures of contraception

**Date of first enrolment**

21/04/2008

**Date of final enrolment**

31/12/2016

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Addenbrooke's Hospital**

Hills Road  
Cambridge  
United Kingdom  
CB2 2QQ

**Study participating centre**

**Birmingham Children's Hospital**

Steelhouse Lane  
Birmingham  
United Kingdom  
B4 6NH

**Study participating centre**

**Royal Bolton Hospital**

Minerva Road  
Bolton  
United Kingdom  
BL4 0JR

**Study participating centre**

**Stepping Hill Hospital**

Poplar Grove  
Stockport  
United Kingdom  
SK2 7JE

**Study participating centre**

**Norfolk and Norwich University Hospital**

Colney Lane  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**

**Elsie Bertram Diabetes Centre**

Norfolk and Norwich University Hospital  
Colney Lane

Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**  
**John Radcliffe Hospital**  
Headley Way  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**  
**Kingsmill Hospital**  
Mansfield Road  
Sutton in Ashfield  
Nottingham  
United Kingdom  
NG17 7AE

**Study participating centre**  
**Queen's Medical Centre**  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**  
**Gloucester Royal Hospital**  
Great Western Road  
Gloucester  
United Kingdom  
GL1 3NN

**Study participating centre**  
**Diabetes Centre**  
Ipswich Hospital NHS Trust  
Heath Road  
Ipswich  
United Kingdom  
IP4 5PD

**Study participating centre**

**Torbay Hospital**

Lawes Bridge  
Torbay  
United Kingdom  
TQ2 7AA

**Study participating centre**

**Royal Blackburn Hospital**

Haslingden Road  
Blackburn  
United Kingdom  
BB2 3HH

**Study participating centre**

**West Suffolk Hospital**

Hardwick Lane  
Bury St Edmunds  
United Kingdom  
IP33 2QZ

**Study participating centre**

**Medicine Guy Hilton Research Centre**

Thornburrow Drive  
Hartshill  
Stoke-on-Trent  
United Kingdom  
ST4 7QB

**Study participating centre**

**Hull Royal infirmary**

Craven Building  
Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre**



**Doncaster Royal Infirmary**  
Armthorpe Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**  
**Stafford Hospital**  
Weston Road  
Stafford  
United Kingdom  
ST16 3SA

**Study participating centre**  
**Leicester Royal Infirmary**  
Infirmary square  
Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**  
**Leighton Hospital**  
Middlewich Road  
Crewe  
United Kingdom  
CW1 4QJ

**Study participating centre**  
**Queen's Hospital**  
Belvedere Road  
Burton upon Trent  
United Kingdom  
DE13 0RB

**Study participating centre**  
**Peterborough City Hospital**  
Edith Cavell Campus  
Bretton Gate  
Peterborough  
United Kingdom  
PE3 9GZ

**Study participating centre**  
**Newham University Hospital**  
Glen Road  
Plaistow  
London  
United Kingdom  
E13 8SL

**Study participating centre**  
**Macclesfield District General Hospital**  
Victoria Road  
Macclesfield  
United Kingdom  
SK10 3BL

**Study participating centre**  
**Royal Victoria Infirmary**  
Queen Victoria Road  
Newcastle upon Tyne  
United Kingdom  
NE1 4LP

## **Sponsor information**

### **Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

### **Sponsor details**

Addenbrookes Hospital  
Box 277, Hills Road  
Cambridge  
United Kingdom  
CB2 2QQ  
+44 1223 348490  
research@addenbrookes.nhs.uk

### **Sponsor type**

Not defined

### **Website**

[http://www.cuh.org.uk/research/research\\_index.html](http://www.cuh.org.uk/research/research_index.html)

ROR

<https://ror.org/04v54gj93>

## Funder(s)

### Funder type

Industry

### Funder Name

Novo Nordisk Pharmaceuticals Limited

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

### Intention to publish date

31/12/2017

### Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version V8	12/01/2013	15/05/2017	No	Yes
<a href="#">Participant information sheet</a>	version V8	12/01/2013	15/05/2017	No	Yes
<a href="#">Participant information sheet</a>	version V8	12/01/2013	15/05/2017	No	Yes
<a href="#">Basic results</a>			20/05/2019	No	No