

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

Submission date 12/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 12/05/2010	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 20/05/2019	Condition category Nutritional, Metabolic, Endocrine	☐ 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

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Contact information

Type(s)

Scientific

Contact name

Ms Diane Picton

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2007-004144-74

Protocol serial number

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

Primary study design

Interventional

Study design

Multicentre randomised interventional treatment trial

Study type(s)

Treatment

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) 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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

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)

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

Funder(s)

Funder type
Industry

Funder Name
Novo Nordisk Pharmaceuticals Limited

Results and Publications

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?
Basic results			20/05/2019	No	No

version V8

Participant information sheet		12/01/2013	15/05/2017	No	Yes
Participant information sheet	version V8	12/01/2013	15/05/2017	No	Yes
Participant information sheet	version V8	12/01/2013	15/05/2017	No	Yes