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

Submission date
12/05/2010

Recruitment status
No longer recruiting

Registration date
12/05/2010

Overall study status
Completed

Last Edited
20/05/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. here 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 insulatard (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) with minimisation of variation in:
1. Age (< or ≥ 16yrs)
2. BMI SDS (< or ≥ 1 SDS)

3. HbA1c (< or ≥ 8 % or 64mmol/mol)
4. Years post menarche (< or ≥ 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 intepretation 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

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?
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
Participant information sheet	version V8	12/01/2013	15/05/2017	No	Yes
Basic results			20/05/2019	No	No