

The effect of insulin detemir on energy balance, postprandial nutrient handling, body fat distribution and adipose tissue metabolism and gene expression in patients with type 2 diabetes

Submission date 30/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/04/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00788840

Clinical Trials Information System (CTIS)
2007-003085-17

Protocol serial number

7771

Study information

Scientific Title

The effect of insulin detemir on energy balance, postprandial nutrient handling, body fat distribution and adipose tissue metabolism and gene expression in patients with type 2 diabetes

Acronym

DRN 274 (DEES)

Study objectives

This is a 24-week, national, single-centre, open-labelled, randomised, parallel-group trial comparing energy expenditure with insulin detemir versus a neutral protamine hagedorn (NPH) insulin using a basal-bolus regimen with insulin aspart as the mealtime insulin in subjects with type 2 diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved (ref: 07/H1102/108)

Study design

Single centre randomised interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Insulin switch, Metabolic

Interventions

Insulin detemir versus NPH insulin using a basal-bolus regimen with insulin aspart as the mealtime insulin in subjects with type 2 diabetes.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Detemir, Insulatard®

Primary outcome(s)

Resting and activity energy expenditure

Key secondary outcome(s)

1. Diet-induced thermogenesis
2. Meal tolerance test analysis of arexigenic and anorexigenic gut hormones
3. Magnetic resonance imaging (MRI) fat distribution

Completion date

01/10/2009

Eligibility

Key inclusion criteria

1. Type 2 diabetes
2. Treated with metformin
3. Already on treatment with a long-acting or intermediate insulin
4. Aged greater than or equal to 18 years of age, either sex
5. HbA1c greater than 7.0%
6. Body mass index (BMI) 27 - 40 kg/m²
7. Able and willing to perform self-blood glucose monitoring
8. Able and willing to maintain consistent eating habits throughout the entire trial period
9. Able and willing to maintain consistent physical activity level during the entire trial period

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

22

Key exclusion criteria

1. Patients on sulphonylureas or thiazolidinediones
2. Proliferative retinopathy that has required acute treatment within the last six months
3. Impaired hepatic or renal functions
4. Cardiac problems
5. Uncontrolled hypertension (treated or untreated)
6. Mental incapacity, unwillingness or a language barrier precluding adequate understanding or co-operation

Date of first enrolment

01/10/2007

Date of final enrolment

01/10/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

CEDAR Centre

Guildford

United Kingdom

GU2 7XX

Sponsor information

Organisation

University of Surrey (UK)

ROR

<https://ror.org/00ks66431>

Funder(s)

Funder type

Charity

Funder Name

Learning about Insulin Bursary for Research and Awareness (LIBRA) (UK)

Results and Publications

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?
Basic results			21/04/2020	No	No