

# 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

<b>Submission date</b> 30/07/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/04/2020	<b>Condition category</b> 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

**EudraCT/CTIS number**  
2007-003085-17

**IRAS number**

**ClinicalTrials.gov number**

NCT00788840

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

GP practice

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Resting and activity energy expenditure

**Secondary outcome measures**

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

**Overall study start date**

01/10/2007

**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/m<sup>2</sup>
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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 30; UK sample size: 30

**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**

England

United Kingdom

**Study participating centre**

**CEDAR Centre**

Guildford

United Kingdom

GU2 7XX

**Sponsor information****Organisation**

University of Surrey (UK)

**Sponsor details**

Division of Nutrition

Faculty of Health and Medical Sciences

Guildford

England

United Kingdom

GU2 7XH

**Sponsor type**

University/education

**Website**

<http://www2.surrey.ac.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

**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="#">Basic results</a>			21/04/2020	No	No