

# 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

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2007-003085-17

### ClinicalTrials.gov (NCT)

NCT00788840

**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/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

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