# A single centre randomised double blind placebo controlled 12 week trial in subjects with type 2 diabetes comparing glycaemic control with insulin glargine in combination with nateglinide or placebo

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
29/09/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	Condition category	Individual participant data
28/10/2010	Nutritional, Metabolic, Endocrine	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Philip Home

#### Contact details

Institute of Cellular Medicine (Diabetes)
The Medical School
Framlington Place
Newcastle
United Kingdom
NE2 4HH
+44 (0)191 222 7019
philip.home@ncl.ac.uk

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

# ClinicalTrials.gov number

# Secondary identifying numbers

N0503172589

# Study information

#### Scientific Title

#### **Study objectives**

A single centre randomised double blind placebo controlled 12 week trial in subjects with type 2 diabetes comparing glycaemic control with insulin glargine in combination with nateglinide or placebo.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Single centre randomised double blind placebo controlled 12 week trial

## Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

# Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

# Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Diabetes

#### **Interventions**

Insulin glargine titrated to a target pre-breakfast blood glucose level of <6.0 mmol/l (all patients) plus either nateglinidine (60mg increasing to 180mg) (intervention arm) or placebo (control arm) before each meal.

Length of follow-up: 12 weeks post randomisation (there was a one week screening period and then four week run in period after recruitment but prior to randomisation)

#### Intervention Type

Other

#### **Phase**

**Not Specified** 

#### Primary outcome measure

- 1. Eight-point self-monitored blood glucose profiles (pre- and 1 h post-meals, bed-time, and 0300-0500 h)
- 2. Hypoglycaemia was classified as symptoms-only (with glucose levels above 3.0 mmol/l [54 mg /dl] or no test data), minor (confirmed ≤3.0 mmol/l), or severe (requiring third party assistance).
- 3. HbA1c measured by DCCT-aligned HPLC (this was the primary outcome)
- 4. Body weight

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/04/2003

#### Completion date

31/12/2004

# Eligibility

#### Key inclusion criteria

- 1. Aged 18 years or over
- 2. Type 2 diabetes (meeting the WHO definition of diabetes)
- 3. Using a human premix or NPH insulin for at least 3 months
- 4. HbA1c of 6.1-10.0 %
- 5. BMI inferior or equal to 42.0 kg/m2
- 6. Both men & women were eligible for recruitment, but women of childbearing potential were required to be using adequate contraception

## Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

**Not Specified** 

# Target number of participants

69 approached, 55 randomised (26 to intervention arm, 29 to control)

## Key exclusion criteria

- 1. Significant hepatic dysfunction
- 2. Significant renal dysfunction
- 3. Active cardiovascular disease

#### Date of first enrolment

01/04/2003

#### Date of final enrolment

31/12/2004

# Locations

# Countries of recruitment

England

**United Kingdom** 

# Study participating centre

Institute of Cellular Medicine (Diabetes)

Newcastle United Kingdom NE2 4HH

# Sponsor information

#### Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

# Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

# Funder type

Government

#### **Funder Name**

Newcastle upon Tyne Hospitals NHS Trust (UK)

# Alternative Name(s)

Newcastle upon Tyne Hospitals NHS Trust

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

Local government

#### Location

**United Kingdom** 

# **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?
Results article	results	01/04/2007		Yes	No