ISRCTN10167754 https://doi.org/10.1186/ISRCTN10167754

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
29/09/2006	No longer recruiting
Registration date	**Overall study status**
29/09/2006	Completed
Last Edited	**Condition category**
28/10/2010	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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