

Randomised controlled trial of nocturnal insulin glargine versus human insulatard in combination with metformin in patients with type two diabetes currently treated with metformin/insulatard combination therapy

Submission date

12/09/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

12/09/2003

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

30/09/2013

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Niall Furlong

Contact details

Research Fellow
Diabetes Centre
Whiston Hospital
Prescot, Merseyside
United Kingdom
L35 5DR
+44 (0)151 426 1600

Additional identifiers

Protocol serial number

N0237101842

Study information

Scientific Title

Study objectives

The aim of the present open-labelled, randomised controlled study is to examine effectiveness of insulin glargine in combination with metformin 1 g twice daily (bid) - 1 g three times a day (tds) compared with insulatard combined with metformin (same dose) in type two diabetic patients currently treated with insulatard/metformin combination therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes

Interventions

Randomised controlled trial. Patients randomised to:

1. Nocturnal insulin glargine
2. Human insulatard in combination with metformin

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Glargine, metformin, insulatard

Primary outcome(s)

1. Glycosylated haemoglobin (HbA1c)
2. Tasting blood glucose
3. Frequency of hypoglycaemia
4. Weight change

Key secondary outcome(s)

Well being and diabetes treatment satisfaction measured using appropriate validated questionnaires.

Completion date

31/07/2003

Eligibility

Key inclusion criteria

80 patients.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2001

Date of final enrolment

31/07/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Research Fellow

Prescot, Merseyside

United Kingdom

L35 5DR

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

St Helens and Knowsley Hospitals NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration