ISRCTN76123473 https://doi.org/10.1186/ISRCTN76123473

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	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/09/2013	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study design
Randomised controlled trial

Primary study design
Interventional

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