

Improving insulin treatment

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 26/07/2016	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ 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 Mark Daly

Contact details

Royal Devon & Exeter Hospital (Wonford)

Barrack Road

Exeter

United Kingdom

EX2 5DW

+44 (0)1392 403086

M.E.Daly@exeter.ac.uk

Additional identifiers

Protocol serial number

N0203125673

Study information

Scientific Title

Improving insulin treatment

Study objectives

Is post-prandial targeting of glucose better than pre-prandial targeting when using insulin glargine and novorapid in combination?

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

Nutritional, Metabolic, Endocrine: Diabetes

Interventions

Randomised Controlled Trial

1. Glargine/novorapid/fasting and post-prandial titration of insulin doses
2. Glargine/novorapid/fasting and pre-prandial titration of insulin doses
30 patients with Type I diabetes will be recruited via clinicians (medical and nursing staff) within the Exeter Diabetes Centre, fully informed and having given written consent. Prior to randomisation, each patient will wear a continuous glucose monitor for 72 hours and have blood samples taken for HbA1c. Each patient will then be randomised to receive one of two treatments. One group will be transferred to the intervention (glargine/novorapid/fasting and post-prandial titration of insulin doses) and followed up for three months. The second group will be randomised to the same insulin regimen but insulin doses will be titrated against pre-prandial and fasting measurements. Both groups will undergo a similar protocol of specialist nurse contact and intensification of their glycaemic control. 72 hours of continuous glucose monitoring system (CGMS) will take place before treatment and at the end of the three month period. Food and exercise diaries will be kept for these periods and patients will be asked to replicate the initial pattern of food and exercise for the second period.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Insulin

Primary outcome(s)

To see if adjusting pre-prandial insulin on the basis of post-prandial measurements is feasible as a clinical approach in the routine clinical situation and to explore the possibility that it might improve overall diabetes control.

Key secondary outcome(s)

Not provided at time of registration

Completion date

22/11/2003

Eligibility

Key inclusion criteria

1. Type 1 diabetes
2. >2 years duration
3. Clinical decision for glargine/novorapid therapy independently of the study
4. Fully informed and consented

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

22/04/2003

Date of final enrolment

22/11/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Devon & Exeter Hospital (Wonford)

Exeter

United Kingdom

EX2 5DW

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Devon and Exeter NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration