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Improving insulin treatment

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/07/2016	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled 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 contact details to request a participant information sheet

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 HbAlc. 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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
22/04/2003

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

Age group
Not Specified

Sex
Both

Target number of participants
30

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
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Devon and Exeter NHS Trust (UK)

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