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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

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

Study design
Randomised controlled trial

Primary study design
Interventional

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 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(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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes