# Improving insulin treatment

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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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

## 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