

# Does oral terbutaline prevent asymptomatic nocturnal hypoglycaemia in children with insulin dependent diabetes mellitus in a clinical setting?

**Submission date**

12/09/2003

**Recruitment status**

No longer recruiting

**Registration date**

12/09/2003

**Overall study status**

Completed

**Last Edited**

13/04/2018

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ 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**

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**Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Does oral terbutaline prevent asymptomatic nocturnal hypoglycaemia in children with insulin dependent diabetes mellitus in a clinical setting?

### Study objectives

Does oral terbutaline prevent asymptomatic nocturnal hypoglycaemia in children with diabetes?

### 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)

Other

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

### Health condition(s) or problem(s) studied

Diabetes

### Interventions

Twenty-five diabetic children will be recruited from the population attending the diabetes clinic in Sheffield. They will be visited at home on three separate occasions by a diabetes research nurse. Following either placebo or one of two doses of terbutaline at bedtime, their blood sugar will be measured every half hour overnight whilst they sleep. Blood samples will be taken from a cannula sited in a vein on the back of the hand after application of an anaesthetic cream. The day before and the day after the overnight study, each child will be asked to do several finger prick glucose measurements using both their usual glucose meter and dried blood spots on to paper. The child's routine should be only minimally disrupted.

### Intervention Type

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Terbutaline

**Primary outcome measure**

The main outcome measures are:

1. Differences in the number of nights when hypoglycaemia occurs between placebo and terbutaline treatment
2. The effect on blood sugar assessed by comparing the children's home blood glucose measurements before/after the bedtime dose

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/11/2002

**Completion date**

28/02/2004

## **Eligibility**

**Key inclusion criteria**

Twenty-five diabetic children will be recruited from the population attending the diabetes clinic in Sheffield

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Both

**Target number of participants**

25

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/11/2002

**Date of final enrolment**

28/02/2004

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Sheffield Children's Hospital**

Sheffield

United Kingdom

S10 2TH

# Sponsor information

## Organisation

Department of Health (UK)

## Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

## Sponsor type

Government

## Website

<http://www.doh.gov.uk>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Sheffield Childrens Hospital 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