

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

☐ Prospectively registered

☐ Protocol

Registration date

12/09/2003

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

13/04/2018

Condition category

Nutritional, Metabolic, Endocrine

☐ 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 NP Wright

Contact details

Division of Child Health
Sheffield Children's Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH
+44 (0)114 222 2000
N.P.Wright@sheffield.ac.uk

Additional identifiers

Protocol serial number

N0220093140

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

United Kingdom

England

Study participating centre

Sheffield Children's Hospital

Sheffield

United Kingdom

S10 2TH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Sheffield Childrens Hospital NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration