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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

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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

Study design
Randomised controlled trial

Primary study design
Interventional

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