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Utility of continuous glucose monitoring (CGMS) in children with type I diabetes on intensive treatment regimens

Submission date 20/12/2004	**Recruitment status** No longer recruiting
Registration date 09/02/2005	**Overall study status** Completed
Last Edited 20/01/2020	**Condition category** Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2001/012

Study information

Scientific Title
Utility of continuous glucose monitoring (CGMS) in children with type I diabetes on intensive treatment regimens

Study objectives
The purpose of this study was to assess the effect on diabetes control of guiding insulin adjustment with four cycles of CGMS over 3 months in children on near-physiological insulin replacement regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was approved by the ethics committee of The Childrens Hospital Westmead.

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

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

Interventions
Two arms:
1. Intervention arm has CGMS monitoring for 3 days every 3 weeks over a 3 month period (4 cycles)
2. Control arm that continues traditional intermittent blood glucose level (BGL) monitoring

Each 3 weeks, the insulin doses will be reviewed and adjusted based on either the CGMS or intermittent BGL data. Change in HbA1c will be compared between the two groups.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Diabetes control, measured using HbA1c and fructosamine measured at baseline and 6 and 12 weeks.

Secondary outcome measures
1. HbA1c, measured using ion-exchange high-pressure liquid chromatography (Bio-Rad Laboratories)
2. Fructosamine, measured using Cobras Integras system

Overall study start date
01/05/2004

Completion date
30/09/2004

Eligibility

Key inclusion criteria
Children and adolescents aged 18 years or less with type one diabetes on either an insulin pump or an intensive insulin plan that includes insulin glargine (Lantus) for at least 3 months.

Participant type(s)
Patient

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
35

Key exclusion criteria
1. Known poor compliance
2. HbA1c greater than 10%

Date of first enrolment
01/05/2004

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
Australia

Study participating centre
Institute of Endocrinology and Diabetes
Westmead NSW
Australia
2145

Sponsor information

Organisation
Institute of Endocrinology and Diabetes, The Children's Hospital at Westmead

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05k0s5494

Funder(s)

Funder type
Industry

Funder Name
Australian Diabetes Society (Australia) - Servier National Action Plan Grant for 2004 (Australia)

Funder Name

Novo Nordisk (Australia) - Regional Diabetes Support Scheme 2005 grant

Funder Name
Medtronic Australasia Pty Ltd (Australia) - donating CGMS sensors and loaning monitors

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/07/2006		Yes	No