

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

☐ Prospectively registered

☐ Protocol

Registration date
09/02/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
20/01/2020

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

18 years

Sex

All

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

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**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