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Glucose Level Awareness (using self-monitoring of blood glucose [SMBG] and continuous glucose monitoring [CGM]) in Diabetes Study

Submission date
18/01/2011

Recruitment status
No longer recruiting

Registration date
18/02/2011

Overall study status
Completed

Last Edited
18/07/2016

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

Protocol serial number
ADC-PMR-NAV-10009

Study information

Scientific Title
Glucose Level Awareness (using self-monitoring of blood glucose [SMBG] and continuous glucose monitoring [CGM]) in Diabetes Study: a multicentre randomised controlled three-arm study

Acronym
GLADIS

Study objectives
To demonstrate clinical benefit of continuous glucose monitoring (CGM) relative to self-monitoring of blood glucose (SMBG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. UK: Sheffield Research Ethics Committee, 21/12/2010, ref: 10/H1308/77
2. Germany: Stuttgart Ethics Committee, 02/12/2010, ref: F-2010-090

Study design
Multicentre randomised controlled three-arm study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Following a 20 day masked (baseline) period using the Freestyle Navigator subjects will be randomised into one of 3 groups for the next 80 days:
1. The first group will wear the FreeStyle Navigator for the remaining duration of the study
2. The second group will wear the FreeStyle Navigator with glucose alarms switched off
3. The third (control) group will manage their blood glucose with standard SMBG and use a FreeStyle Navigator masked for two, 20-day periods between 40 to 60 days and 80 to 100 days

For all 3 groups, subjects will complete Quality of Life Questionnaires and have HbA1c measurements at both baseline and day 100.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Time spent outside of glucose target: no alarms versus SMBG (days 80 - 100)

Key secondary outcome(s))
1. Time spent outside of glucose target: no alarms versus CGM (days 80 - 100)
2. Time spent outside of glucose target: CGM versus SMBG (days 80 - 100)
3. Time spent outside of glucose target (days 40 - 60)
4. HbA1c

5. Average glucose (days 40 - 60 and 80 - 100)
6. Glucose variability (days 40 - 60 and 80 - 100)
7. Quality of life measures
8. Adverse events

Completion date
01/05/2012

Eligibility

Key inclusion criteria
Inclusion criteria as of 13/03/2012:
1. Subject with type 1 or type 2 diabetes on multiple daily injections (MDI) (3 or more insulin injections per day) or continuous subcutaneous insulin infusion (CSII) for greater than 6 months prior to study enrolment
2. Aged 18 - 65 years, either sex and, in the Investigator's opinion, thought technically capable of using CGM
3. HbA1c between 7% and 11% (inclusive) for previous HbA1c test obtained within 3 months prior to enrolment
4. Subject reporting testing of blood glucose an average of 2 - 7 times per day

Previous inclusion criteria
1. Subject with type 1 or type 2 diabetes on multiple daily injections (MDI) (3 or more insulin injections per day) or continuous subcutaneous insulin infusion (CSII) for greater than 1 year prior to study enrolment
2. Aged 18 - 65 years, either sex and, in the Investigator's opinion, thought technically capable of using CGM
3. HbA1c between 7.5% and 10% (inclusive) for previous HbA1c test obtained within 3 months prior to enrolment
4. Subject reporting testing of blood glucose an average of 2 - 7 times per day

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Subject has known allergy to medical grade adhesives
2. Subject has concomitant disease or condition that influences metabolic control or, in the investigators opinion, may compromise patient safety

3. Subject is participating in another study of a glucose monitoring device or drug that could affect glucose measurements or glucose management
4. Subject is currently using another continuous glucose monitoring device or has used real-time continuous glucose monitoring in the last 6 months
5. Subject is pregnant/planning to become pregnant within the planned study duration

Date of first enrolment
31/01/2011

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
United Kingdom

England

Germany

Study participating centre
Salford Royal NHS Foundation Trust
Stott Lane
Salford
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M6 8HD

Sponsor information

Organisation
Abbott Diabetes Care Ltd (UK)

ROR
https://ror.org/03wnay029

Funder(s)

Funder type
Industry

Funder Name

Abbott Diabetes Care Ltd

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	01/05/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes