

# 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

Prospectively registered

Protocol

**Registration date**  
18/02/2011

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
18/07/2016

**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

Dr John New

### Contact details

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Salford  
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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

United Kingdom

M6 8HD

## Sponsor information

**Organisation**

Abbott Diabetes Care Ltd (UK)

**ROR**

<https://ror.org/03wnay029>

## Funder(s)

**Funder type**

Industry

**Funder Name**

## 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?
<a href="#">Results article</a>	results	01/05/2015		Yes	No