Randomised Controlled Study to Evaluate the Impact of Novel Glucose Sensing Technology on Hypoglycaemia in Type 1 Diabetes.

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The primary objective of this study is to demonstrate the impact on time in hypoglycaemia (number of hours per day of hypoglycaemic excursions < 3.9 mmol/L, 70 mg/dL) using the Abbott Sensor Based Glucose Monitoring System compared to Self…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON42217

Source
ToetsingOnline

Brief title
IMPACT

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, diabetes mellitus type 1

Research involving
Human

Sponsors and support

Primary sponsor: Abbott Diabetes Care

Source(s) of monetary or material Support: Abbott Diabetes Care

Intervention

Keyword: diabetes type 1, glucose, hypoglycaemia, sensor

Outcome measures

Primary outcome

Difference between the Intervention and Control arm in the number of hours/day in hypoglycaemia (glucose < 3.9 mmol/L [70 mg/dL]) for the 14 day period at 6 months (Visit 7 to Visit 8).

Secondary outcome

Visit 3 (Day 45) Interim Analysis (Intervention Arm Only)

Difference in TIR defined as 3.9 to 10.0 mmol/L (70 to 180 mg/dL) in the 14 day period between Days 31 to 45 of Treatment Phase as compared to the Baseline phase (Days 1 to 15). Safety data will also be analysed and reported (includes AEs and insertion site signs and symptoms).

Final Analysis (Intervention and Control Arms)

o HbA1c

o Proportion of subjects who achieve time spent in hypoglycaemia (<70 mg/dL) * 1 hour/day

o TIR defined as 3.9 to 10.0 mmol/L, (70 mg/dL to 180 mg/dL)

o Average glucose and glucose variability

o Number and duration of hypoglycaemic episodes (< 3.9 mmol/L, 70 mg/dL); analysis overall and by both day and night (night defined as between 11 pm and 6 am)

o Number of severe hypoglycaemic episodes (defined as hypoglycaemia episodes

requiring assistance by a third person and/or hospitalisation)

o Number and duration of hypoglycaemic episodes (< 3.1 mmol/L, 55 mg/dL)

o Number and duration of hypoglycaemic episodes (<2.2 mmol/L, 40 mg/dL)

o Number and duration of hyperglycaemic episodes (> 10.0 mmol/L, 180 mg/dL)

o Number and duration of hyperglycaemic episodes (> 13.3 mmol/L, 240 mg/dL)

o Number of events of symptomatic hypoglycaemia

o Post prandial hyperglycaemia (> 10.0 mmol/L, 180 mg/dL)

o Number of episodes of DKA

o Total daily dose of insulin

o Prandial to basal insulin ratio

o Number of subjects changing from once daily to twice daily basal insulin

o Body weight and body mass index

o Fasting cholesterol and triglycerides

o Blood pressure

o User questionnaire (subject [Intervention arm only] and health care professional facing)

o Quality of Life/Patient Reported Outcome Measures (including Hypoglycaemia Fear Survey, diabetes treatment satisfaction questionnaire, diabetes distress scale, and diabetes quality of life)

o Emergency room visits / admissions and non protocol related additional clinic time

o Medication usage (non insulin related, including glucagon, self reported from event diary)

o Number of blood glucose finger stick tests performed

o Number of Sensor scans performed (Intervention arm only).

Safety Endpoints

o AEs

o Sensor insertion site signs and symptoms.

Additional Analyses

o Subgroup analysis by MDI and CSII

o All data from the 3 month time point will be analysed and reported for the primary endpoint and relevant secondary endpoints (excludes questionnaires and cholesterol and triglyceride measures) at study completion.

Study description

Background summary

This medical device is expected to provide a clinical benefit for diabetes management. Standard blood glucose measurement for patients often painful and tedious because of the invasive nature. As a result, compliance with the glucose measurement is often insufficient, leading to a deterioration in control of the disease. This medical device is a large amount of data gathering in a much less invasive way. Expected that patients will often perform this glucose test, learn to anticipate better and faster intervention itself and can achieve. Better control of their disease

Study objective

The primary objective of this study is to demonstrate the impact on time in hypoglycaemia (number of hours per day of hypoglycaemic excursions < 3.9 mmol/L, 70 mg/dL) using the Abbott Sensor Based Glucose Monitoring System compared to Self Monitoring Blood Glucose (SMBG) testing.

Study design

A prospective, multi-centre, randomised, controlled, two arm treatment study to assess the impact on time in hypoglycaemia (number of hours per day with hypoglycaemic excursions < 3.9mmol/L, 70 mg/dL) using the Abbott Sensor Based Glucose Monitoring System.

The treatment period for both arms will be 208 days.
Control arm subjects will have 2 masked Sensor wears (Visits 5 to 6 and Visits 7 to 8)
One scheduled interim analysis of the intervention subjects is planned at the point when all Intervention arm subjects complete 45 days of study involvement. (Only time in range [TIR] and safety data (Adverse Events [AEs] and insertion site signs and symptoms) will be analysed and evaluated at this point).

89 control (SMBG arm) subjects are required to complete the treatment phase of the study.
89 intervention (Sensor arm) subjects are required to complete the treatment phase of the study.
A minimum of 224 subjects with Type 1 diabetes are required to be randomised to obtain a minimum of 178 subjects completing the study. 178 is the minimum required to detect a difference of 30% (0.3 hours/day at a mean of 1.0 hour/day) in time spent below 3.9 mmol/L (70 mg/dL) at the 6 month time point.(Day 208).
Subjects are planned to be recruited from approximately 30 sites in the European Union.

Intervention

For all participating subjects 4x 3mL blooddraw by Venapunction

Study burden and risks

The burden is relatively low and does not differ significantly from normal burden experienced by the patients of this disease. It is expected that the load sensor for the group will be even lower than those of their standard method of diabetes management, in connection with the less invasive nature of this system. For the control group, there is essentially no difference in invasiveness compared with the standard treatment. The load consists mainly of reports (diaries and questionnaires).

Contacts

Public
Abbott Diabetes Care

Range Road N/A
Witney, Oxon OX29 0YL
GB
Scientific
Abbott Diabetes Care

Range Road N/A
Witney, Oxon OX29 0YL
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

o Diagnosed with Type 1 diabetes for * 5 years
o On their current insulin regimen for * 3 months prior to study entry
o Screening HbA1c result * 7.5% (58 mmol/mol)
o Reports self testing of blood glucose levels on a regular basis equivalent to a minimum of 3 times daily for at least 2 months prior to study entry
o In the investigator*s opinion the subject is considered technically capable of using the Abbott Sensor Based Glucose Monitoring System
o Aged 18 years or over.

Exclusion criteria

o Subject has been diagnosed with hypoglycaemic unawareness (i.e. subject has a diagnosis of impaired awareness of hypoglycaemia recorded in their medical notes OR in the investigator*s opinion the subject currently experiences less than minimal warning symptoms for impending hypoglycaemia)
o Subject is currently prescribed animal insulin
o Subject is currently prescribed oral steroid therapy or is likely to require oral steroid therapy for any acute or chronic condition during the study
o Has known allergy to medical grade adhesives
o Currently participating in another device or drug study that could affect glucose measurements or glucose management
o Currently using a Continuous Glucose Monitoring (CGM) device or has used one within the previous 4 months

o Currently using Sensor augmented pump therapy
o Is planning to use a CGM device at any time during the study
o A female subject who is pregnant or planning to become pregnant within the study duration
o A breast feeding mother
o Currently receiving dialysis treatment or planning to
receive dialysis during the study
o Has a pacemaker
o Has experienced an acute myocardial infarction within previous 6 months
o Has a concomitant disease or condition that may compromise subject safety including; unstable coronary heart disease, cystic fibrosis, serious psychiatric disorder, or any other uncontrolled medical condition
o Has experienced an episode of confirmed or suspected diabetic ketoacidosis (DKA) in the previous 6 months
o In the investigator*s opinion, the subject is considered unsuitable for inclusion in the study for any other reason.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-09-2014
Enrollment:	84
Type:	Actual

Medical products/devices used

Generic name:	Abbott Sensor Based Glucose Monitoring System
Registration:	No

Ethics review

Approved WMO Date:	28-07-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-09-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-03-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-08-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48612.098.14