User evaluation of the 'free style Navigator continuous glucose monitoring system

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

Summary

ID

NL-OMON31154

Source
ToetsingOnline

Brief title
Navigator continuous glucose monitoring system

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Abbott
Source(s) of monetary or material Support: Abbott Diabetes Centre

Intervention

Keyword: Continuous glucose monitoring system, Diabetes mellitus type 1, Glycaemic control

Outcome measures

Primary outcome

Primary study outcome is the degree of glycaemic variability, comparing the blinded period (days 0 tot 20) with the open period (days 20 to 60). Glucose variability is a mathematical outcome, derived from the glucose data from the first and second period of the Navigator-device. This outcome parameter is exemplified on page 27 of the protocol.

Secondary outcome

Secondary outcome parameter is the experiences of the users with this new device. Patients fill in a questionnaire after completion of the study.

Study description

Background summary

Optimal glycaemic control is an important goal in the treatment of patients with diabetes mellitus. Optimal glycaemic control decreases the risk of developing chronic organ complications. In addition, prevention of acute hypoglycaemic and hyperglycaemic episodes is an important goal. Measuring the blood glucose level is an essential method to improve glycaemic control. Patients measure the blood glucose levels themselves in capillary blood obtained by finger stick. With these values a daily glucose profile can be made and this profile, in combination with factors like nutrition and physical exercise, is used to adjust the treatment with glucose-lowering drugs like insulin.

Glucose profiles comprise generally of two to seven measurements during the day. These measurements give however only a 'snapshot' picture of glucose control and there is a desire to obtain more detailed information on the glucose levels in order to improve glucose control. This is even more important

in those patients who can not be treated satisfactorily at all with the current, classic methods to construct glucose profiles.

Continuous subcutaneous glucose monitoring is a recently developped technique using an subcutaneously inserted needle, impregnanted with a glucose-measuring enzyme, allowing frequent glucose determinations in the interstitial fluid compartment. Levels are given every 5 minutes. On the basis of these frequent levels, a detailed picture of daily glucose control is provided. With first devices, glucose levels could only be displayed 'off line' after disconnecting the device and downloading the data. Although the analysis of the detailed glucose profile has a great educational effect, there is a need for devices that can display directly, 'on line' the glucose results. The 'free style navigator continuous glucose monitoring system' is such a 'on line' device. In addition to 'on line' display there is the possibility to set threshold alarms: the device warns with an auditory and vibration signal when the glucose level falls below or surpasses the individually-set lower or the upper threshold, respectively. The most innovative feature of the 'Navigator' is the dynamic alarm function. This means that the alarms go off with a change in glucose level in a specific period of time above an individually-set threshold. For example, an alarm can be set at a change of more than 5 mmol/l per 10 minutes. This is irrespective of the absolute glucose level. In practice, both specific absolute and dynamic thresholds are used. These innovations can in theory provide a method to further extend the methods to measure glucose levels in order to improve glucose control.

Study objective

The objective of the study is the assessment of the effect of the use of the 'free style navigator continuous monitoring system' on the glucose variability in patients with type 1 diabetes mellitus. This assessment is combined with the analysis of the patient experiences with this devices.

Study design

This is a study that comproses two sequential periods. During the first period of 20 days the devices is worn but the glucose levels are not displayed. During the next second period of 40 days, the device is worn and the device displays 'on line' the glucose levels.

Intervention

The intervention is the use of the 'free style navigator continuous glucose monitoring device' with an number of facilities:
1: 'On line' display of the glucose level in the insterstitial fluid every 5 minutes
2: Alarm features with fixed, individually set glucose upper and lower

thresholds
3: Alarm features using a dynamic threshold, that is an individually set change in glucose level in a specific time period

Before the start of the intervention (Day 0) and after the end of the intervention (Day 60) a blood sample will be drawn to determine HbA1c and fructosamine (both indices of longer term glycaemic control). Frustosamine gives a reflection of glycaemic control during the last 2 tot 3 weeks HbA1c during the last 2 months.

Study burden and risks

The burden and risk associated with the study are firstly wearing the device and inserting the sensor (measuring device) into the subcutaneous tissue. Insertion takes places every 5 days; insertion is done with a little, specially designed device. The sensor is basically similar to the sensor that is used with the 'off line' glucose monitoring system. With insertion, a little bleeding can occur and pain can be experienced. After some days, the insertion place can become red as a consequence of an inflammatory reaction. In that case the sensor is removed and a new one inserted at another place.
Secondly, patients are confronted with actual glucose results, alarms outside fixed glucose levels and alarms outside a fixed change in glucose level over a period of time. This may mean a certain mental burden. In practice this has not be proven to be a problem and in depth assessment of one's own glucose profile is part and parcel of the study as well as normal practice.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Type 1 diabetes mellitus since at least 2 jaar
Age at least 18 years

Exclusion criteria

1: Severe hypoglycaemia during the last 4 months before the start of the study
2: Medical problems (co-morbidity, organ complications of diabetes) of medication that would potentially jeopardize the participation of the patient in the eyes of the treating physician and/or the investigator
3: Pregnancy or planned pregnancy during the study period
4: Participation in another study with a comparable device

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Free style navigator continuous glucose monitroign system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-11-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL19619.041.07