Sensing With Insulin Pump Therapy to Control HbA1c

Published: 14-04-2008
Last updated: 10-05-2024

To determine whether patients with Type 1 diabetes mellitus in sub-optimal glycemic control can achieve better glycemic control as evidenced by a drop in HbA1c using the Medtronic MiniMed Paradigm® REAL-Time Pump and the continuous Glucose...

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

Summary

ID

NL-OMON31759

Source
ToetsingOnline

Brief title
Sensing With Insulin Pump Therapy to Control HbA1c

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic Inc.

Intervention

Keyword: glycemic controlinsulin pumpcontinuous glucose monitoring

Outcome measures

Primary outcome

To determine whether patients with diabetes mellitus can achieve better glycemic control as evidenced by a drop in HbA1c of 0.3%.

Secondary outcome

To determine whether patients with Type 1 diabetes mellitus in sub-optimal glycemic control using PRT compared to CSII alone with SMBG can achieve:

*Reduced glycemic variability

*Increased time in euglycemia

*Reduced occurrence of hypo- and hyperglycemia

*Improved treatment satisfaction

*Reduced number of severe hypoglycemic events

*Reduced number of diabetic ketoacidosis events

*Changed treatment patterns: total daily insulin dose, basal patterns, basal/bolus ratio, number of daily boluses, types of boluses and timing

*Reduced total number of admissions to emergency room and hospitalizations (number and duration) due to diabetic-related events

*Reduced number of days missing school (children/adolescents) or missing work (adolescents/adults), due to diabetic-related events

Study description

Background summary

Improving glycemic control in people with diabetes, has been shown to decrease risks of micro-vascular, neurological, and renal complications associated with the condition[1]. The landmark DCCT trial [1] also clearly established that achieving an HbA1c of 7.0% or less through an intensive insulin therapy (IIT) can reduce or delay the incidence and onset of diabetic complications.

In current clinical practice IIT with multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII) is well established to lower and maintain average glucose levels. Nevertheless, patients trying to reduce their HbA1c often achieve this at the expense of increased risk of hypoglycemia.

Reaching target HbA1c levels depends upon monitoring blood glucose (BG) levels and titrating therapy to reduce glycemic excursions. Reducing glycaemic excursions minimizes the risk of acute complications of hypoglycaemia and diabetic ketoacidosis. Strict glycemic control is more difficult to achieve with MDI, due to variability in absorption[4] and timing of insulin injections. This reason often precipitates a switch to CSII. Several studies have shown superiority of CSII over MDI regarding clinical outcomes[2-11] and quality of life [5-13] .

The majority of patients assess their BG through self monitoring blood glucose (SMBG) using fingerstick measurements, to assess and adjust their therapy. Nevertheless, many patients perform SMBG tests infrequently due to inconvenience, pain, or therapy burden. Using only SMBG as reference point to establish glycemia profiles results in a certain amount of missed hyper- and hypoglycemic events every day [14-15]. Moreover, the DCCT trial[1] showed that subjects in the IIT arm experienced a 3.3 fold higher incidence of severe hypoglycemia than the control group despite performing SMBG four or more times daily.

It is possible to avoid missing hyper- and hypoglycemic excursions with the development of new devices which continuously measure and display continuous glucose values. Several studies using these devices have demonstrated that availability of continuous glucose values helps patients reduce hyper- and hypoglycemic excursions, and improve HbA1c values [16-21]. In 2006, Deiss et al[22] published the first randomized controlled clinical trial evaluating whether Type 1 patients using MDI or CSII, in poor glycemic control could improve HbA1c using a continuous glucose monitor, the Guardian REAL-Time®. This trial demonstrated a significant reduction in HbA1c over 3 months.

Study objective

To determine whether patients with Type 1 diabetes mellitus in sub-optimal glycemic control can achieve better glycemic control as evidenced by a drop in HbA1c using the Medtronic MiniMed Paradigm® REAL-Time Pump and the continuous Glucose Monitoring System versus the Medtronic MiniMed Paradigm® REAL-Time Pump alone with Self Monitoring Blood Glucose (SMBG).

Study design

This study is a randomized, two-arm, controlled, cross-over, multi-center trial in adult and pediatric subjects in Europe. There is a wash out period between the two treatment phases.

The study is a post-market release trial, as all study devices and related software (see section 5.3) are CE marked.

Study burden and risks

There are possible risks and side effects connected to the device and followed procedures. Possible additional risks include the following (although others are possible):

*Skin irritation, bruising, discomfort, redness, bump, bleeding, irritation, pain, rash, infection, appearance of a small *freckle-like* dot where the sensor needle was inserted, local infection at sensor site and allergy to sensor components or dressing.

If irritation of the insertion site is noted, then the sensor will be removed. It is recommended to wear the glucose sensor for 3 days. If it is worn for longer periods it may cause such problems. To ensure correct placement of the sensor and to minimize discomfort upon insertion, an insertion device (Sen-Serter) will be used to insert the sensor (Sen-Serter will be provided to you at the beginning of the study treatment).

*Alarms may alert you that you are too high or too low, and on checking your blood glucose with a fingerstick, you may find that the value is acceptable. Nevertheless it can happen that the alarm alerts you unnecessarily. This should be discussed with your physician so that the alarms can be adjusted.

*Inaccurate glucose values or inappropriate alarms provided by the device could result in inappropriate administration of insulin or ingestion of carbohydrates. Such inappropriate treatment decisions could result in exacerbation of the symptoms associated with hypoglycemia and hyperglycemia.

Such risks can be minimized if you always follow the instruction to confirm any

hypoglycemia, hyperglycemia alarms or symptoms using the glucose meter prior to taking any action based on the alarm or displayed glucose values.

In case of risks outweighing the benefits for your well-being, your physician or Medtronic can decide to terminate your participation in the clinical study.

Contacts

Public
Medtronic B.V.

Earl Bakkenstraat 10
NL-6422 PJ Heerlen
Nederland
Scientific
Medtronic B.V.

Earl Bakkenstraat 10
NL-6422 PJ Heerlen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

*Type 1 diabetes mellitus diagnosed for at least 12 months prior to signature of informed consent,
*Sub-optimal glycemic control (7.5%*Patient treated by continuous subcutaneous insulin infusion (CSII) for at least 6 months prior signature of informed consent.
*Patient treated within the practice of the investigator*s center at least 6 months prior

signature of informed consent.
*Patient has no preliminary experience with the sensor function of the PRT or the Guardian® REAL-Time for the 4 months prior signature of informed consent.

Exclusion criteria

Existing pregnancy or intention to conceive (as assessed by investigator).
*Hearing or vision impairment so that glucose display and alarms cannot be recognized.
*Three or more incidents in the last 12 months of severe hypoglycaemia with documented BG below 50mg/dL (if possible), resulting in unconsciousness, hospitalisation or third party assistance, where recovery follows treatment with glucose or glucagon or similar.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	14-04-2008
Application type:	First submission

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
Other	CCT-NAPN-17327
CCMO	NL21232.098.07