A Prospective, Multi-Center Evaluation of the Accuracy of a Novel Continuous Implanted Glucose Sensor

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

Summary

ID

NL-OMON40657

Source
ToetsingOnline

Brief title
PRECISE

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, Diabetes type 1

Research involving
Human

Sponsors and support

Primary sponsor: Senseonics, Incorporated
Source(s) of monetary or material Support: Senseonics;Incorporated

Intervention

Keyword: Continuous Glucose Monitoring system, Diabetes, Fully implantable sensor

Outcome measures

Primary outcome

Mean absolute relative difference (MARD) of Sensor readings compared with the reference measurements (YSI) at successive 30-days intervals through 180 days post-insertion.

Secondary outcome

1. Additional accuracy measures during the period of Sensor use * mean absolute difference; median absolute relative difference; agreement as expressed by readings within 20%, 30% and 40% of reference values; trend accuracy measured over time at different glucose rates of change and starting ranges.

2. Clarke Error Grid, Consensus Error Grid and Continuous Glucose Error Grid.

3. Deming regression analysis

4. Bland Altman analysis

5. Low/High glucose alert/alarm performance * accuracy of detection of hypo- and hyperglycemic states; sensitivity and specificity.

(The glucose alert and alarm performance of the Senseonics CGM System will be evaluated through post-processing of data collected)

Study description

Background summary

The Senseonics Continuous Glucose Monitoring System is a glucose monitoring device indicated for continually measuring interstitial fluid glucose levels in

adults with diabetes for the operating life of the sensor. The Senseonics Continuous Glucose Monitoring System is intended to be used:
* To aid in the management of diabetes.
* To provide real-time glucose readings directly to the user.
* To provide glucose trend information.
* To provide alarms for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

Continuous glucose monitoring has proven to be an adequate and effective method to improve diabetes treatment in patients with type 1 diabetes.
Safety, accuracy and reliability are essential components of a good functioning sensor system and should therefore be assessed in clinical trials.

Study objective

The purpose of this clinical investigation is to evaluate the accuracy of the Senseonics Continuous Glucose Monitoring System (Senseonics CGM System) measurements when compared with reference standard measurements (YSI glucose analyzer). The investigation will also evaluate safety of the Senseonics CGM System usage, while in the clinic and during home use.

Study design

This is a prospective, single-arm multi-center investigation enrolling approximately 15 (a total of 82 in Europe) adult subjects with diabetes mellitus. Subjects will be screened for inclusion and exclusion criteria and informed consent obtained. Each subject will have two Sensors inserted on Visit 2 (Day 0), one Sensor in each upper arm. One of the Sensors in each subject will be designated as the *primary Sensor.* A subset of subjects will have the Sensor in their selfreported dominant arm designated as the primary Sensor and a subset of subjects will have the Sensor in their self-reported non-dominant arm designated as the primary Sensor. The investigation will include 11 in-clinic visits: a screening visit to determine subject eligibility, one 3-hour visit (on Visit 2, Day 0) to insert the Sensors, three 8-hour daytime visits (on Visits 5, 7, and 9; Days 30, 90, and 150) and five 24-hour overnight visits (on Visits 3, 4, 6, 8, and 10; Days 1, 14, 60, 120, and 180), to evaluate Sensor performance, removal of the Sensors at the completion of Visit 10 (on Day 180) and a final visit (Visit 11, Day 190) to evaluate healing of Sensor insertion/removal sites. Between in-clinic visits, subjects will wear an external Transmitter over the primary designated Sensor for data collection in the home except during charging, bathing or any other water activity. Subjects will not wear an external Transmitter over the secondary designated Sensor in the home.
Subjects will be given access to the glucose data collected on the primary designated sensor Transmitter (*primary Transmitter*), including glucose alerts/alarms, during home use only. Data collected on the secondary designated

sensor Transmitter (*secondary Transmitter*) during the in-clinic visits will be used to evaluate the precision of the Senseonics CGM System.

Intervention

Each subject will have two Sensors inserted on Visit 2 (Day 0), one Sensor in each upper arm. One of the Sensors in each subject will be designated as the *primary Sensor.* A subset of subjects will have the Sensor in their selfreported dominant arm designated as the primary Sensor and a subset of subjects will have the Sensor in their self-reported non-dominant arm designated as the primary Sensor. Sensor performance will be assessed by comparing sensor measurements to reference methods for measuring bloodglucose.

Study burden and risks

The duration of the of the study for each patient will be between 190 and 220 days (including 11 hospital visits, 149 hours). Risk to the patient includes haematoma or infection around the blood collection catheter sites or the sensor insertion/ removal site. The risk of hypo- and hyperglycaemia is present in every patient with Type 1 diabetes. There is a risk of anemia due to frequent blood sampling with an estimated maximum blood loss due to blood withdrawal of 275.5 mL in a period of 8 weeks.

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

1. Males and Females Aged *18 years of age.
2. Clinically confirmed diagnosis of diabetes mellitus for a duration of 1 year and uses insulin therapy for their diabetes management (including subjects on insulin pump therapy).
3. Subject understands study procedures and risks, is willing to comply with protocol requirements, and has signed an informed consent document.

Exclusion criteria

1. History of severe hypoglycemia in the last 6 months prior to study start.
2. Severe diabetic ketoacidosis in the past 6 months.
3. Any condition preventing or complicating the placement, operation or removal of the Sensor including upper extremity deformities or skin condition.
4. Any medical condition or illness that in the judgment of the investigator might interfere with the procedures, results or compliance during the course of this investigation, or increase the risk of induced hypoglycemia or repeated blood testing including significantly impaired hepatic function and renal failure.
5. Known microvascular (diabetic) complications, including active proliferative diabetic retinopathy or macular edema, active nonproliferative retinopathy, diabetic nephropathy including active retinopathy, or neuropathy.
6. Hematocrit >50% or <30%
7. Females pregnant or intending to become pregnant during the course of the investigation.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2014
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Senseonics Continuous Glucose Monitoring System (Senseonics CGM System)
Registration:	No

Ethics review

Approved WMO Date:	24-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	16693
CCMO	NL48503.018.14