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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27554

Source
NTR

Brief title
PRECISE

Health condition

Diabetes Mellitus

Sponsors and support

Primary sponsor: Senseonics Inc.
20451 Seneca Meadows Parkway
Germantown, Maryland, 20876
Source(s) of monetary or material Support: Senseonics Inc.
20451 Seneca Meadows Parkway
Germantown, Maryland, 20876

Intervention

Outcome measures

Primary outcome

The primary effectiveness endpoint will be evaluated in a test of superiority to a pre-specified performance goal for accuracy. Mean absolute relative difference (MARD) of Sensor readings will be compared with the reference measurements (YSI) at successive 30-days intervals through 180 days post-insertion. for reference glucose values greater than 75 mg/dL (4.2 mmol/L

Secondary outcome

1. Mean absolute difference for reference glucose values less than 75 mg/dL (4.2 mmol/L).
1.2. 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

Study description

Background summary

The Senseonics CGM System consists of : (1) a small Sensor, (approximately 3.3 mm [0.130”] diameter x 15.7 mm [0.620”] length) which has a ring that elutes the steroid dexamethasone; (2) a battery-powered external Transmitter (“Transmitter”); and (3) a Mobile Medical Application (MMA) for display of glucose information that runs on a Handheld Device (HHD). Accessories to the system include a blunt dissector for creating a pocket under the skin and an insertion tool used to place the Sensor into the pocket. The Transmitter, worn externally over the Sensor insertion site, powers the Sensor and receives signals from the Sensor across the skin. The Sensor does not contain a battery or other stored power source; instead it is powered discretely, as needed, by a simple inductive magnetic link between the two components. Between readings, the Sensor remains electrically dormant and fully powered down. At each query (set to a default of approximately every two minutes with a duration of 60 milliseconds) the Transmitter first sends the power (via magnetic link) to activate the Sensor, then uses this same magnetic link to capture the reading. This operational mode is commonly referred to as “speak when spoken to.” Finally, the Transmitter calculates the measured glucose value, the rate of change in glucose and all alarms that need to be alerted to the user. This information is then transmitted via Bluetooth Low Energy with AES-CCM encryption to the Mobile Medical Application and the subject is alerted to the alarms through activation of the vibratory motor within the Transmitter. The Mobile Medical Application displays glucose values, trends, and graphs as well as alerts. The Transmitter also contains digital storage media that enable extended data and profile information to be retrieved, downloaded to a computer or other electronic device, and reviewed by the physician or subject.

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

N/A

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Males and Females ≥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).

Exclusion criteria

1. History of severe hypoglycemia in the last 6 months prior to study start
2. 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-05-2014
Enrollment:	82
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4328
NTR-old	NTR4476
Other	Senseonics Trial : CTP-0004

Study results