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

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27554

Bron
NTR

Verkorte titel
PRECISE

Aandoening

Diabetes Mellitus

Ondersteuning

Primaire sponsor: Senseonics Inc.
20451 Seneca Meadows Parkway
Germantown, Maryland, 20876
Overige ondersteuning: Senseonics Inc.
20451 Seneca Meadows Parkway
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	30-05-2014
Aantal proefpersonen:	82
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4328
NTR-old	NTR4476
Ander register	Senseonics Trial : CTP-0004

Resultaten