A Feasibility Trial to Evaluate the Senseonics Continuous Glucose Monitoring System

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The purpose of this clinical investigation is to evaluate the effectiveness of modified Sensor designs on the longevity (up to a maximum of 90 days) of the Senseonics Continuous Glucose Monitoring (CGM) System. The investigation will also evaluate...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON40094

Source
ToetsingOnline

Brief title
The Senseonics CGM-System Feasibility Trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
insulin-dependent diabetes mellitus, Type 1 diabetes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Fully implantable self-monitoring Blood Glucose Meter, Interstitial fluid glucose levels, Type 1 diabetes

Outcome measures

Primary outcome

The primary objective of this investigation is to assess accuracy and longevity

of the Senseonics CGM System modifications and to assess safety of the

Senseonics CGM System during up to 90days of Sensor use in the clinic and

during home use.

System modifications include evaluating the biocompatible coatings

hydroxyethylmethacrylate (HEMA) and polyethylene glycol diacrylate (PEG) with

or without PET. These coatings are on the outer surface of the Sensor and are

designed to improve the accuracy and/or longevity of the

System.

Secondary outcome

The secondary objectives of this investigation are as follows:

• To determine other relevant Senseonics CGM System performance measures.

• To evaluate the incidence of procedure and device-related adverse events in

clinic and home use.

• To evaluate the incidence of all adverse events in clinic and home use.

Study description

Background summary

Diabetes, unless carefully monitored and treated, can cause severe, long-term

medical complications. It is the leading cause of adult blindness, end-stage renal disease and lower-limb amputations, and significantly increases the risk for heart disease and stroke. Compliance with glucose monitoring regimens is one of the key tools for improving metabolic control. The current standard glucose-monitoring regimen for patients with diabetes involves obtaining a *fingerstick* or alternative blood glucose multiple times a day to obtain a capillary blood sample for testing. According to the International Society of Pediatric and Adolescent Diabetes (ISPAD), *successful application of intensified diabetes management with multiple injection therapy or insulin infusion therapy requires frequent self-monitoring of blood glucose (four to six times a day) and regular, frequent review of the results to identify patterns requiring adjustment to the diabetes treatment plan.* Despite this diagnostic procedure and therapeutic intervention, glucose values of patients with diabetes fluctuate widely throughout the day. In addition, the uncomfortable, cumbersome nature of this test regimen leads to poor compliance of the patients with this procedure.

Study objective

The purpose of this clinical investigation is to evaluate the effectiveness of modified Sensor designs on the longevity (up to a maximum of 90 days) of the Senseonics Continuous Glucose Monitoring (CGM) System. The investigation will also evaluate the safety of the Senseonics CGM System during clinical use as well as during home use with a blinded display.

Study design

This is a display-blinded, single-center, prospective clinical study in 12 subjects. Subjects will be screened for inclusion and exclusion criteria and informed consent obtained. Each subject will have two Sensors inserted subcutaneously on Day 0 (upper arm(s) and/or abdomen). Inserted devices will remain in-vivo for a period of up to 90 days. Sensors inserted in all subjects will be powered and read in-vivo, as well as tested in-vitro after removal, to further quantify Sensor performance. Subjects will also be issued a home blood glucose meter for use in the clinic and at home during the home wear portion.

Intervention

LET OP VANAF HIER MOET NOG!

Subjects will receive two Sensor insertions during Visit 2 (Day 0). Subjects will not be required to fast prior to the visit. Vital signs, fingerstick glucose and β-HOB (β-hydroxybutyrate) levels will be measured. If the subject is female, a urine HCG test will be performed. If the subject meets in-clinic

visit eligibility criteria, he/she will proceed with two Sensor insertions according to the methods described in Appendix 2. Subjects will have 2 Sensors inserted in the upper arms and/or abdomen. Readers will be placed over the Sensors and readings will be taken for approximately 2 hours. Subjects will be assigned a study SMBG (self monitored blood glucose) meter and will be trained on its proper use.

Study burden and risks

This investigation will be conducted by investigators who are qualified by training and experience in the treatment of diabetes mellitus. In addition, adequate measures including eligibility criteria limitations, subject screening and pre-visit assessment of the diabetic condition have been incorporated into the clinical investigation to minimize such risks. Investigators have also been trained in the technique for Sensor insertion and removal. Investigators will examine the insertion site during each in-clinic visit and document any suspected adverse event. Subjects will be instructed to contact the clinic immediately upon any sign of extreme irritation or discomfort. Furthermore, potential risks associated with participation in this investigation will be minimized and managed in accordance with ISO 14155: Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practices, regulations imposed by the Competent Authority and requirements of the approving Ethics Committee(s).

The Sponsor believes that any potential risk presented by this investigation has been minimized and that adequate testing, safeguards, and safety monitoring have been incorporated into the investigation to further minimize and mitigate the risks.
The Sponsor firmly believes that the value of the knowledge to be gained by conducting this clinical investigation to demonstrate the safety and accuracy of the Senseonics CGM System outweighs the potential risks posed to participating subjects.

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. Females and males aged >=18 to <=65 years of age.
2. Clinically confirmed diagnosis of Type 1 diabetes mellitus (for at least 1 year of duration) on multiple daily injections (>2 injections per day) or on insulin pump therapy.
3. HbA1c <=10%.
4. Subject understands study procedures and risks, is willing to comply with protocol requirements, and has signed an informed consent document.

Exclusion criteria

Subjects will be denied participation in the investigation if they meet any of the following key, exclusion criteria:
1. History of severe hypoglycemia in the 6 months immediately prior to study start.
2. Severe diabetic Ketoacidosis in the past 6 months.
3. Females who are lactating, pregnant or intending to become pregnant during the course of the investigation, defined as
3.1 Not postmenopausal for at least 1 year OR
3.2 Not surgically sterile, OR
3.3 If of child bearing potential, the subject is not practicing birth control, not willing to avoid pregnancy for the period of study participation, has a positive serum pregnancy test at screening or has a positive urine pregnancy test at the time of the Sensor insertion procedure.
4. Any condition preventing or complicating the placement, operation or removal of the Sensor, including but not limited to:

4.1 Upper extremity deformities that would impede the placement of the Sensor or application of the external Reader.
4.2 Any skin condition that may affect Sensor insertion or external Reader placement.
5. 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 but not limited to:
5.1 Anemia, defined as either:
5.1.1 Hemoglobin (Hgb) value for females of < 12.0 g/dl, for males < 13.0 g/dl OR
5.1.2 Abnormal red cell indices and iron deficiency.
5.2 History of hepatitis B, hepatitis C or HIV.
5.3 Symptomatic coronary artery disease, unstable angina, myocardial infarction or stroke within 6 months of screening, uncontrolled hypertension, or congestive heart failure.
5.4 Any seizure disorder.
5.5 History of adrenal insufficiency.
5.6 Significantly impaired hepatic function
5.7 Renal failure, defined as any prior dialysis or an estimated glomerular filtration rate (eGFR) below 60 mL/min per 1.73 m2 using CKD-EPI formula (Levey et al, 2009)
6. Known microvascular (diabetic) complications (other than non-proliferative retinopathy), including active proliferative diabetic retinopathy or macular edema, non-proliferative retinopathy stage 3, diabetic nephropathy (other than microalbuminuria with normal creatinine), gastroparesis or neuropathy requiring treatment.
7. Currently receiving any of the following therapies, or likely to need such treatment during the follow-up period of this study:
7.1 Immunosuppressant therapy
7.2 Chemotherapy for any form of cancer
7.3 Anti-coagulant therapy (e.g. Plavix, LMW heparin, coumadin)
7.4. Chronic systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled)
7.5. Antibiotic treatment for chronic infection (e.g. osteomyelitis)
8. Magnesium <1.6 mg/dL at screening.
9. Potassium <3.4 mmol/L at screening.
10. Hematocrit >50% or <30% at screening.
11. Topical or local anesthetic allergy.
12. Known current or recent alcohol or drug abuse by subject history.
13. Participation in another clinical investigation within 30 days preceding screening, or intention to participate in any other clinical investigation during the period of this study.
14. The presence of any other active implanted device, whether turned on or off. Passive implants are allowed.
15. A condition requiring or likely to require the use of magnetic resonance imaging (MRI).
16. Positive drug screen results
17. Any condition that in the investigator*s opinion would make the subject unable to complete the study. Investigator will supply rationale.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	SMSI Subcutaneous Continuous Glucose Monitoring System
Registration:	No

Ethics review

Approved WMO

Date:	28-05-2013
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	NL42737.041.12