Reveal LINQ Usability Study

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See protocol page 23This study is designed to assess the usability and functionality of the Reveal LINQ system. Data from the first 30 patients, with 30 days of follow-up, will be used to assess sensing performance and wireless capabilities of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON38774

Source
ToetsingOnline

Brief title
Reveal LINQ

Condition

- Cardiac arrhythmias

Synonym
arrhythmia, Syncope

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: AF detection, Functionality, Insertable Cardiac Monitor, Reveal LINQ

Outcome measures

Primary outcome

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The primary objective is to evaluate the Reveal LINQ system functionality.

Specifically:

* Assess the percentage of successful wireless transmissions

* Characterize sensing performance

o Signal amplitude and quality of R-wave amplitude at implant and 1

month

Secondary outcome

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The secondary objectives are to evaluate the Reveal LINQ device specificity for arrhythmia detection and to assess the safety and efficacy of the Reveal LINQ system. The following will be assessed through 1 month post-insertion in Phase I subjects, with subsequent analyses performed at 12 months post-implant in all subjects:

- Report the System Related Adverse Events

- Report the Procedure Related Adverse Events

- Comparison of sensing/detection accuracy compared to Holter monitoring for AF

- Assessment of AF detection

- Evaluate physician satisfaction with the insertion procedure and insertion

tools

- Evaluate physician satisfaction of data access and ease of use

- Evaluate patient satisfaction Physician/Patient Survey

- Evaluate physician satisfaction with the explant procedure and any adverse

events

Study description

Background summary

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Medtronic*s current Reveal DX/XT Insertable Cardiac Monitor (ICM) offers unique diagnostic monitoring insights to cardiologists managing their patients at risk of syncope or arrhythmias. The Reveal DX/XT ICM can aid physicians in determining whether symptoms such as fainting, dizziness, palpitations, and unexplained seizure-like episodes have cardiovascular cause and may help to uncover asymptomatic arrhythmias.

Reveal LINQ is a new ICM system that records subcutaneous ECG.

The Reveal LINQTM has many of the same features as the currently marketed Reveal XT. The primary improvements include a reduced device size; wireless telemetry; the addition of the pwave algorithm for AF detection and a new format for data accessibility/review.

Study objective

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This study is designed to assess the usability and functionality of the Reveal LINQ system. Data from the first 30 patients, with 30 days of follow-up, will be used to assess sensing performance and wireless capabilities of the Reveal LINQsystem (Phase I). The data from the remaining 120 subjects will also assess performance of the AF algorithm (Phase II).

Study design

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The Reveal LINQ study is a prospective, non-blinded, non-randomized, multi-center clinical trial.

Subjects will have required follow up visits at baseline/ implant, 1 month, 6 months and 12 months. Subjects will transmit device data via manual interrogation on a weekly basis during the first month in addition to a nightly wireless data transmission using the MyCareLink® home monitor.
All subjects will be requested to wear an external Holter for 48 hours at approximately 4 weeks post-insertion. Following the 1 month follow-up visits, subjects will transmit device data via manual interrogation on a monthly basis until study exit. All subjects (Phase I and Phase II) will complete the 12 month follow-up period and be exited at their 12 month follow-up visit.

It is required for pre-ablation subjects to complete the initial 30 day monitoring period prior to the ablation procedure.

Intervention

The following interventions are additional for all subjects in the;

- Short-patient assessment at implantation, 1, 6, and 12 months
- 48h Holter at 1 month visit
- Xray at implantation and 1 month
- Weekly manual CarleLink transmission till 1 month follow-up, and a monthly transmission till 12 month follow-up (is end of study)

Study burden and risks

See protocol page 54-56

Risk associated with a device implant and followed procedures.
Possible additional risks for participating in this study include the following:
* It can happen that for example by loss of contact no signal of noise is detected by the Reveal LINQ. The Reveal LINQ would indicat that there is a Fast VT or an asystole which in reality is not the case.
* The electrodes used with the DR220 Holter recorder might cause mild skin discomfort or irritation
* Study sponsor may decide to stop the study before getting approval of the investigational product. This may limit those centers having the supporting investigational software for future follow-up needs.
* There may be other discomforts and risks related to the Reveal LINQTM device and/or this study that are not foreseen at this time.
* There may be unforeseen risk to pregnant women or to the embryo or fetus.

Subject may benefit from the smaller size of the Reveal LINQ compared to previous ICM models. Besides that the Reveal LINQ Usability Study may offer no direct personal benefit to individual subjects. Subjects may benefit from continuous ECG monitoring with the Reveal ICM, as this monitoring could result in diagnosis of AF (or other arrhythmias) and comprehensive evaluation of symptoms on an earlier and more conclusive basis than what would be possible without an implantable monitor. Subjects may also benefit from being evaluated more frequently in the office according to the study visit schedule.

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

Subject is indicated for a Reveal device
o Phase I (initial 30 subjects): Any indication for a Reveal LINQ Device

o Phase II (after the initial 30 subjects): Subject has atrial fibrillation and is indicated for and identified as an AF pre-ablation candidate

Exclusion criteria

* Subject has an active implanted cardiac medical device (e.g., IPG, ICD, CRT).
* Subject is unwilling or unable to comply with the study procedures

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Reveal LINQ
Registration:	No

Ethics review

Approved WMO

Date:	28-08-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL44628.060.13
Other	nog niet bekend