Multicenter, prospective evaluation of performance, safety, and surveillance of the WiCS-LV System in patients indicated for Cardiac Resynchronization Therapy

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

Summary

ID

NL-OMON34226

Source
ToetsingOnline

Brief title
Wireless Stimulation Endocardially for CRT

Condition

- Cardiac arrhythmias

Synonym
Wireless Stimulation Endocardially for Cardiac Resynchronization Therapy

Research involving
Human

Sponsors and support

Primary sponsor: EBR Systems Inc.

Source(s) of monetary or material Support: EBR Systems Inc.

Intervention

Keyword: Cardiac Resynchronization Therapy, Endocardial Stimulation, Wireless

Outcome measures

Primary outcome

Primary study objectives:

Safety

Safety of the device has been defined as

- Device-related complications (24 hour peri-operative and one

month)

- Procedure -related complications (24 hour peri-operative and one

month)

Performance

Performance of the device has been defined as:

- Bi-ventricular pacing capture (documented on 12 lead EKG at one

month)

Secondary outcome

Secondary study objectives:

Safety

1.Device-related complications up to 6 months

2. Major complications up to 6 months

3. Surveillance evaluation annually for 5 years

Performance

1. Left ventricular pacing capture (documented on 12 lead EKG at one,

3 and 6 months)

2. Bi-ventricular pacing capture (documented on 12 lead EKG at 3 and

6 months)

3. Bi-ventricular pacing on 24 hour ambulatory monitoring at 1, 3,

and 6 month

Preliminary efficacy

1. Clinical composite score (all cause mortality, HF hospitalization,

NYHA class, and patient global assessment (16)) at 6 months

2. Change in echocardiographic left ventricular end-systolic volume,

left ventricular end-diastolic volume, and ejection fraction at 6 months

3. Change in blood laboratory Brain Natriuretic Peptide (NT-proBNP)

at 6 months

Study description

Background summary

Bi-ventricular pacing is the pacing modality used to accomplish Cardiac Resynchronization Therapy (CRT). CRT is recommended for use by both European Society of Cardiology/European Heart Rhythm Association (ESC/EHRA) Guidelines and ACC/AHA/HRS Guidelines for a number of subsets of heart failure patients based on evidence from large scale randomized trials demonstrating benefits in symptoms, function, and survival.

Study objective

The purpose of this Clinical Investigation Plan is to collect data on the safety and performance of the WiCS-LV system. It is designed to satisfy requirements for clinical data and post market clinical follow-up for the

Active Implantable Medical Devices Directive (AIMDD 90/385/EEC), Annex 7, as amended in December 2008. A complete risk assessment was performed to determine the design of the Clinical Investigation Plan.

Study design

This study is a multicenter, prospective, open-label, non-comparative clinical investigation,
conducted in up to 11 clinical sites in Europe and one clinical site in Hong Kong, Republic of China.

Intervention

Pre-implant visit
•Physical exam
•Cardiac medications
•Chest X-ray
•EKG*s
•Global assessment
•NYHA functional class
•Echocardiogram
•Blood specimens (serum creatinine, electrolytes, BUN, platelet count, NT-proBNP)

Pre-discharge visit
•Physical exam
•Cardiac medications
•Chest X-ray
•EKG*s
•Blood specimens (serum creatinine, electrolytes, BUN)
•WiCS, co-implant device checks
•Adverse events

1-month follow-up visit (± 1 week)
•EKG*s
•24 hr ambulatory monitor
•WiCS, co-implant device checks
•Adverse events

3-month follow-up visit (± 2 week)
•EKG*s
•24 hr ambulatory monitor
•NYHA functional class
•WiCS, co-implant device checks
•Adverse events

6-month follow-up visit (± 1 month)
•Physical exam
•Cardiac medications
•EKG*s
•24 hr ambulatory monitor
•Global assessment
•NYHA functional class
•Echocardiogram
•Blood specimens (NT-proBNP)
•WiCS, co-implant device checks
•Adverse events

1, 2, 3, 4, 5 year follow-up visit (± 2 month)
•Cardiac medications
•EKG*s
•Global assessment
•NYHA functional class
•Echocardiogram
•Blood specimens (NT-proBNP)
•WiCS, co-implant device checks
•Adverse events

Study burden and risks

Patient Benefit and Risks
A risk analysis according to ISO 14971 Application of risk management to medical devices has been conducted. Risks have been proven minimized or eliminated through appropriate design control, confirmed by pre-clinical bench, laboratory and animal testing.

Discomforts and Risks
The WiCS-LV system is associated with some potential discomforts and risks common to all implantable pacing systems, as well as certain unique potential discomforts and risks.

Potential discomforts and risks common to all implantable pacing systems include the following:

Air embolism
Allergic reactions to medications used including renal failure from contrast media
Arrhythmias
Cardiac tamponade
Chronic nerve damage
Death
Electrochemical burns
Excessive bleeding

Excessive fibrotic growth
Foreign body reaction
Hematoma
Embolization of device or materials
Infection
Migration of device
Myocardial tissue injury or perforation
Myocardial infarction
Pain
Pneumothorax
Radiation skin burns
Stroke or transient cerebrovascular episodes
Thromboembolism
Vascular damage

Potential discomforts and risks of the WiCS-LV system not associated with implantable pacing systems but having similarities to left heart catheterization or the implantation of other devices within the left heart (such as stents, clips, septal closure devices, and appendage occlusion devices) include the following:

Aortic or mitral valve damage
Dissection of aorta or branch vessels
Femoral artery pseudoaneurysm
Embolization of device or material, thrombi, or air to systemic circulation increasing stroke and peripheral vascular occlusion risk

Potential discomforts and risks of the WiCS-LV system not associated with implantable pacing systems but having similarities to other diagnostic and therapeutic devices utilizing ultrasound energy (such as ultrasound imaging instruments, physical therapy) related to ultrasound bioeffects include the following:

Thermal injury from ultrasonic transducer elements overheating
Mechanical injury causing tissue damage

These risks are minimized by operating at substantially lower levels (duty cycle and amplitudes) than those used in commercially available echocardiographic imaging instruments. The system has safeguard circuitry to prevent energy levels from exceeding programmed limits.

There is one potential risk of the WiCS-LV system not associated with other devices:

There is a risk that an implanted Electrode will receive ultrasound pulses from other ultrasound devices (such as echocardiographic imaging instruments) and convert those pulses to stimulation pulses. This risk is minimized by the very

short, narrow pulse durations used in echocardiographic imaging devices and by limiting the electrical output of the Electrode to amplitudes lower than the expected stimulation thresholds at these pulse durations.

Potential Benefit
Left ventricular endocardial stimulation using wireless transmission of ultrasound energy in combination with a conventional pacing system is an investigational, non-approved means to accomplish Cardiac Resynchronization Therapy i.e. bi-ventricular cardiac pacing for the treatment of heart failure. CRT in general has been shown to improve patient symptoms, function, and survival (3-11). Small published studies have suggested that CRT using endocardial LV stimulation is associated with better LV function (17-20). The potential for clinical benefit using the approach in this clinical investigation is unknown.

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

In this study, patients providing informed consent will be enrolled responding to the following criteria:;Patients with standard indications for CRT based upon the most recent ESC/EHRA guidelines AND meeting criteria for one of these three categories:
1. Patients with previously implanted pacemakers or ICD*s and meeting standard indications for CRT - referred to as *upgrades*
2. Patients in whom attempted coronary sinus lead implantation for CRT has failed - referred to as *untreated*
3. Patients with previously implanted CRT device, not responding to CRT (no change or worsening of symptom or NYHA functional class after 6 months of treatment confirmed by investigator) - referred to as *non-responders*;Previously implanted or newly implanted CRT*s, pacemakers and ICD devices must provides dual-chamber pacing (RA and RV) if the patient has sinus rhythm, single-chamber pacing (RV) if the patient is in permanent AF

Exclusion criteria

Study patients responding to the following criteria are excluded from participation:
1. Inability to comply with the study follow-up or other study requirements
2. Contraindication to heparin
3. Contraindication to both chronic anticoagulants and antiplatelet agents
4. Contraindication to iodinated contrast agents
5. Intracardiac thrombus by transesophageal echocardiography
6. Age less than 18 years
7. Attempted IPG implant within 3 days
8. Life expectancy of < 12 months
9. Chronic hemodialysis
10. Myocardial infarction within one month
11. Major cardiac surgery within one month
12. Female of childbearing potential, pregnant, or breastfeeding
13. Noncardiac implanted electrical stimulation therapy devices

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):	16-02-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	WiCS-LV system
Registration:	No

Ethics review

Approved WMO

Date:	04-10-2010
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL32645.075.10