Serial, integrated, non-invasive mapping of electro-mechanical activation of the human heart under various pacing conditions.

Published: 11-11-2011
Last updated: 01-05-2024

To perform a human study demonstrating a detailed analysis of electrical and mechanical activation under different cardiac pacing conditions and to describe the accompanying hemodynamic response.Objectives:To demonstrate non-invasive mapping…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON40063

Source
ToetsingOnline

Brief title
Non-invasive mapping of cardiac electro-mechanical activation patterns.

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
heart failure, heart rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W,Medtronic B.V.,Medtronic Trading B.V. The Netherlands

Intervention

Keyword: electro-mechanical activation, Non-invasive

Outcome measures

Primary outcome

The altered pathway of electrical and mechanical activation of the human heart and the accompanying hemodynamic response.

Electrical activation:

Electrical activation patterns of the human heart. Periods of conduction (pq-time, qrs-duration, qtc-time).

Mechanical activation:

Left ventricle (LV) contraction pattern. LV ejection fraction, stroke volume, end-diastolic pressure and volume of left ventricle.

Hemodynamics of patient during study.

Quality of life during study.

Cardiac Electrical activation times registered simultaneously during EPS in patients suffering from arrhythmias and in individuals in whom structural heart disease is ruled out.

Atrial scar in patients after ablation therapy.

Secondary outcome

(serious) adverse events

Study description

Background summary

The pathway of electrical- and subsequent mechanical activation of the human heart is altered by implantation of a cardiac pacemaker. However, assessment and analysis of these alterations have been challenging throughout the years. Recent technological developments allow non-invasive mapping of both electrical- and mechanical activation patterns of the human heart. Improved insight in electrical activation and the accompanying hemodynamic response may contribute to optimization of the quality of life (QOL) of pacing candidates and improve pacing efficacy in general.

Study objective

To perform a human study demonstrating a detailed analysis of electrical and mechanical activation under different cardiac pacing conditions and to describe the accompanying hemodynamic response.

Objectives:

To demonstrate non-invasive mapping electromechanical activation is reliable and clinical applicable on a routine base.

To perform an integrated study on the electro-mechanical relationship under normal and pathological conditions

Integration and interpretation may provide a roadmap to predict and improve clinical effects of cardiac pacing.

To demonstrate the feasibility of monitoring and optimizing cardiac resynchronization therapy (CRT) candidates with non-invasive arterial pulse contour measurements (NAPCM).

To compare effectiveness of non-invasive arterial pulse contour measurements (NAPCM) with conventional echocardiography derived parameters to improve response to cardiac resynchronization therapy (CRT).

To assess the feasibility of cardiac MRI (CMR) for the detection of atrial fibrosis.

Study design

Prospective, observational, multicenter, follow-up study. Study duration has been defined as a maximum of two years.

Study burden and risks

Of participants a baseline cardiac MRI is required to provide detailed anatomy, a prerequisite for correct interpretation of Body Surface Map technology. In case an ablation is carried out following the EPS in patients suffering from atrial fibrillation, an MRI scan with contrast will be repeated in order to assess atrial scar tissue.

This diagnostic modality can cause nausea, headache or general discomfort, especially in subjects suffering from claustrophobia. A contrast agent will be used in order to perform late enhancement MR imaging. This contrast agent can cause nausea or vomiting and is contra-indicated in patients with renal failure. Patients participating in this study have to visit the outpatient department more frequently than other patients with an implanted pacemaker. They will be seen at six-month intervals during the study period instead of at nine-month intervals for non-participants with a pacemaker (regular patients).

Contacts

Public
HagaZiekenhuis

Leyweg 275
Den Haag 2545 CH
NL
Scientific
HagaZiekenhuis

Leyweg 275
Den Haag 2545 CH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Humans of at least 18 years old
Cardiac conduction disorder for which implantation of pacemaker is indicated
Rhythm disorders for which electrophysiological examination is performed.

Exclusion criteria

Humans younger than 18 years old.
Individuals not capable of providing informed consent.
Women of child bearing age and not on reliable birth control program/pregnant women.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	08-12-2011
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-09-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL38156.098.11