Mapping for Acute Transvenous Phrenc nerve Stimulation Study

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Protocol page 17The Mapping for Transvenous Phrenic Nerve Stimulation Study (MAPS) is being conducted to evaluate the feasibility of transvascular stimulation of phrenic nerves via an EP catheter advanced into the great veins.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON41783

Source
ToetsingOnline

Brief title
MAPS Study

Condition

- Sleep disturbances (incl subtypes)

Synonym
Sleep apnea

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Phrenic Nerve, Sleep apnea, Stimulation, Transvenous

Outcome measures

Primary outcome

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To evaluate the feasibility of acute transvenous electrical stimulation of the phrenic nerves to elicit diaphragm movement in patients undergoing a cardiac catheterization involving right heart catheterization and/or EP procedures and/or device implant, as measured by the proportion patients responding.

Secondary outcome

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Evaluate the feasibility of acute transvenous electrical stimulation of the phrenic nerves to elicit inspiration in patients undergoing a cardiac catheterization involving right heart catheterization and/or EP procedures and/or device implant, as measured by the proportion patients responding.

Characterize 1) diaphragm movement and if feasible 2) inspiratory response to changes on stimulation parameters (electrode configuration, amplitude, frequency, and pulse width).For each of the tested anatomical positions, the proportion of patients with capture will be plotted as function of the stimulation parameters (electrode configuration, amplitude, frequency, and pulse width).

Characterize other potential physiologic changes or side effects associated with transvenous nerve stimulation. All observed side effects like potential physiologic changes or side effects associated with transvenous nerve stimulation such as pain, hiccup, skeletal muscular tremor, nausea, sinus node activation will be listed, with number of patients in which the effect was seen. For side effects that appeared frequently, the relation with stimulation position and parameters will be investigated.

Study description

Background summary

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Approximately 100 million individuals are suffering from moderate-to-severe obstructive sleep apnea (OSA) worldwide. In addition, there is a significant overlap between sleep apnea patients and cardiovascular disease; such as heart failure, atrial fibrillation, and bradycardia
To treat sleep apnea in heart failure patients a possible solution could be the extension of leads (which are placed with the tip intra-cardially) with intravenous electrodes.

Study objective

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The Mapping for Transvenous Phrenic Nerve Stimulation Study (MAPS) is being conducted to evaluate the feasibility of transvascular stimulation of phrenic nerves via an EP catheter advanced into the great veins.

Study design

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This is a prospective, non*randomized, acute feasibility study.

Intervention

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Phrenic nerve stimulation

Study burden and risks

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The potential risks to a subject participating in this study are believed to be similar to those encountered during EP procedures, right heart catheterization procedures, and device implants.
These include, but are not limited to, the following:
* Electrical current leakage
* Infection
* Injury to the heart or major blood vessels due to direct contact of EP catheter.
* Pain from stimulation of nerves and/or muscles located in the region of the great veins
* A blood clot in the heart, lung, or veins.

Contacts

Public
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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 undergoing a cardiac catheterization involving right heart catheterization and/or EP procedures and/or device implant.

Exclusion criteria

Subject with a previously implanted transvenous lead, which is still present in the veins under study.
Subject with evidence of phrenic nerve palsy.
Subject with chronic obstructive pulmonary disease.
Subject with a spinal cord stimulator.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2014
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Zie protocol pagina 12;15;16 en 17
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	30-01-2015
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
ClinicalTrials.gov	NCT01981590
CCMO	NL51098.060.14