AF Septal pacing

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Primary Objective: To evaluate the feasibility to obtain a stable position of a ring of stimulation electrodes on the interatrial septum.Secondary objective: *Localized Atrial Capture: evaluate if during the rapid pacing phase of the dual-stage...

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

Summary

ID

NL-OMON45568

Source
ToetsingOnline

Brief title
AF Septal pacing

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrilation, palpitations

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic BRC B.V.

Intervention

Keyword: ablation, atrial fibrillation, pulmonary vein., septal

Outcome measures

Primary outcome

To regard pacing site stability, the number of electrodes that are successfully placed will be counted. For this purpose, the pacing threshold must be less than 10mA at a pulse width of 1ms and no ventricular capture should occur when stimulation occurs with twice the atrial pacing threshold.

Secondary outcome

To assess Localized Atrial Capture the following endpoints will be considered:

*The number of AF episodes in which local capture is recorded during atrial septal stimulation in at least one of the electrode positions
*The number of electrodes for which local capture is determined using pacing schemes with various pacing cycle lengths (PCL) for a duration of 10-30 seconds depending on when capture occurs, at the start of the scheme followed, if feasible, by slow pacing for 1.5 s at 180% AFCL, initiated by a single stimulus at 130% AFCL.
*The spatial extend of capture (assessed from the atrial electrograms recorded from the multipolar right atrial catheter and the multipolar coronary sinus catheter) to obtain local atrial capture obtained with septal pacing of AF, will be assessed off-line after the study procedure.

To assess whether AF termination can be obtained using a dual-stage septal pacing scheme, the surface ECG will be analyzed and the PCL and stimulation

current used, will be noted to measure the number of subjects in which the

pacing scheme successfully terminates the AF episode.

Study description

Background summary

The proof to treat atrial fibrillation (AF) with pacing is restricted. These treatment are interesting because they are safe and not expensive.
With a computer model a pacing schedule is developed in which it is possible to capture the AF in the local atria.
It was not possible to terminate the AF by stimulation with 1 electrode, but is was possible with 4 electrodes.
This is also tested in pigs with positive results. Clinical studies show that pacing on the septum is safe with 1 electrode. because the anatomy of the pigs heart is different from humans, it could be that the optimal placing of the catheter to the septum is not optimal for humans.
Also the safety of stimulation with 4 electrodes and the efficacy to obtain capture and if feasible to terminate the algorhytm of AF needs to be investigated.

Study objective

Primary Objective: To evaluate the feasibility to obtain a stable position of a ring of stimulation electrodes on the interatrial septum.

Secondary objective:
*Localized Atrial Capture: evaluate if during the rapid pacing phase of the dual-stage septal pacing scheme (rapid pacing followed by a step-wise transition to slow-pacing) from multiple electrodes on the interatrial septum, local atrial capture can be observed during atrial fibrillation.
*AF Termination Scheme: evaluate if AF termination can be obtained using a dual-stage septal pacing scheme (rapid pacing followed by a step-wise transition to slow-pacing) from multiple electrodes on the interatrial septum.

Study design

Non-randomized, non-controlled, acute, single-arm research study

Intervention

After the patient has undergone the ablation procedure, there is a waiting time of half an hour. During this time we want to conduct the study. The patient

then already has monitor catheters in the right atrium and the coronary sinus from the standard procedure. The septal catheter will be passed through the septum through a puncture and placed against the left atrial septal wall.
1. In case the patient has sinus rhythm a test will be done whether the placement of this catheter is stable. For this purpose, the pacing thresholds and impedances will be tested.
Also a test will be done to confirm that no ventricle arrhythmia can be induced during the pacing testing

Subsequently, atrial fibrillation will be induced by high frequency pacing. The atrial fibrillation cycle length is then determined. Hereafter, it is investigated if capture of atrial fibrillation occurs. This is investigated per electrode and if all 4 electrodes are used at the same time.
The pacing scheme consists of a range of percentages of the atrial fibrillation cycle length for 10-30 seconds until capture occurs, followed by a stepwise transition to sinus rhythm via an atrial fibrillation cycle length of 130% and 180%.

2. In case the patient has atrial fibrillation, first a test will be done to confirm that no ventricle arrhythmia can be induced during the pacing test. After this the pacing tests will performed with multiple electrode combinations. In case the pacing test does not stop the atrial fibrillation, a cardio-version will be done so the patient will get a sinus rhythm. During sinus rhythm the pacing thresholds and impedances will be tested.

Study burden and risks

The study procedure is performed during the half hour waiting time of the standard procedure. A new pacing therapy is being developed to terminate AF. There is no direct benefit for the subject. AF must be induced by high frequency pacing and if the patient does not come out of it spontaneously and also if the therapy appears to be ineffective, the patient will be cardioverted during sedation.

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

* Patient referred to the center to undergo ablation of the pulmonary vein using radiofrequency (initial AF ablation, or redo procedure).
* In case of paroxysmal AF the right atrium should be dilated as indicated by > 29 ml mm2 or the left atrium should be dilated as indicated by > 34 ml mm2.
* Patient is willing and able to cooperate with the study procedure .
* Patient is willing and able to cooperate with the study procedure.
* Patient is willing and able to sign provide the Informed Consent for their participation in the study.

Exclusion criteria

* Patients under 18 years or over 80 years old.
* Women who are currently pregnant or have a positive pregnancy test.
* Patients with an implantable cardiac device
Patients who already underwent an AF septal ablation procedure.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2018
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	NCT03242941
CCMO	NL61292.100.17