Reduction of AF ablation Induced Thrombo-Embolic Incidence Pilot Study

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Primary Objective:To demonstrate that the AlCath Flux eXtra Gold ablation catheter is non-inferior compared to historical datafrom the literature regarding the prevention of new subclinical cerebral thromboembolic lesions after PVI.Secondary...

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

Summary

ID

NL-OMON43627

Source
ToetsingOnline

Brief title
REDUCE-TE Pilot Study

Condition

- Cardiac arrhythmias

Synonym
Arrhythmia, atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Biotronik SE & Co. KG
Source(s) of monetary or material Support: Biotronik SE & Co. KG

Intervention

Keyword: Atrial fibrillation, Catheter Ablation, Thromboembolism

Outcome measures

Primary outcome

The occurrence of one or more new subclinical cerebral TE lesions after PVI assessed by Diffusion-Weighted MRI.

Secondary outcome

To assess the impact of PVI on the patient*s neurocognitive status.

Endpoint: Neurocognitive score

To assess the incidence of peri-procedural serious adverse events.

Endpoint: Any serious adverse event occurring during the ablation procedure and within 24 hours from completion of the procedure.

To assess the incidence of post-procedural clinical Thromboembolic events (TE).

Endpoint: Composite endpoint: Occurrence of Transient Ischemic Attack and/or Ischemic Stroke and/or Systemic Embolism during the three months post-ablation period (excluding peri-procedural events).

To assess the acute procedural success rates of PVI.

Endpoint: Acute procedural success of PVI, defined as electrical isolation of all Pulmonary veins.

To collect procedure and ablation related data regarding PVI.

Endpoints: Delivered Radio Frequency (RF) power during PVI, Number of RF applications for PVI,Total duration of RF application and delivered energy for PVI, Occurrence of audible steam pops during PVI, Total procedure time (from first puncture to obtain vascular access to removal of the last catheter), Left atrial procedure time (from first left atrial access to removal of all catheters and sheaths from the left atrium)

To assess the rate of success of PVI at three months.

Endpoint: Three months ablation success, defined as freedom from symptomatic AF recurrences off antiarrhythmic drug therapy assessed to three-month follow-up.

Study description

Background summary

Pulmonary Vein Isolation (PVI) is a commonly performed catheter ablation procedure for treatment of patients with symptomatic atrial fibrillation (AF). The procedure is aimed at electrical isolation of the pulmonary veins by the creation of circumferential lesions around the right and left pulmonary Vein (PV) ostia. Successful PVI prevents the recurrence of AF by eliminating AF triggers located within the PV ostia and altering the arrhythmogenic substrate near the atrial-PV junction.. Current clinical guidelines recommend catheter ablation for patients with symptomatic paroxysmal or persistent AF in whom antiarrhythmic drug therapy fails to sufficiently suppress AF recurrences and associated symptoms.
Radio-frequency (RF) ablation utilizes RF energy that is delivered through an ablation catheter to the tissue targeted for ablation. By achieving high local current densities within the target tissue a heat-induced lesion is created. Open irrigation is a technology to cool the ablation tip during RF application, reducing char and the risk of heat coagulation at the tip and possible embolization of coagulum. Thereby it reduces the risk of thromboembolic (TE) complications associated with the application of RF energy. Recent technological developments are aimed at improving the cooling effect by the use of novel electrode materials and an optimized configuration of the irrigation holes.

Peri-procedural thromboembolism is one of the most significant complications of catheter ablation. In a 2010 survey covering more than 20 000 catheter ablation procedures, stroke and Transient Ischemic Attack (TIA) were observed in 0.23% and 0.71% of the procedures, respectively. Besides symptomatic TE events, cerebral thromboembolism may also occur without any acute clinical symptom. Silent cerebral thromboembolic
lesions, resulting from asymptomatic thromboembolism are usually identified by cerebral Diffusion-Weighted Magnetic Resonance Imaging (DW-MRI), which is highly sensitive to acute ischemic injury. Recent literature reports on an incidence of PVI associated silent cerebral embolism detected by DW-MRI between 7.4% and 14%.
Until now, no association has been demonstrated between silent cerebral embolism and neurocognitive impairment. Most silent cerebral lesions observed acutely after ablation may disappear at later follow-up (> 2 weeks post-ablation) and heal without scarring.
Although the impact of silent cerebral embolism on neurological functioning is not demonstrated it is considered a serious issue and reduction of its incidence is desirable.
The REDUCE-TE Pilot study will assess the incidence and neurological consequences of silent cerebral thromboembolism after PVI conducted according to insights and recommendations from guidelines and expert consensus. Furthermore, the study will test the hypothesis that an innovative design and material of the RF ablation electrode, aimed at optimal electrode cooling, will have no higher incidence of silent cerebral
thromboembolism compared to historical data from the literature using irrigated standard catheters (Thermocool, Biosense Webster; Coolpath, St. Jude; Sprinklr, Medtronic).

Study objective

Primary Objective:
To demonstrate that the AlCath Flux eXtra Gold ablation catheter is non-inferior compared to historical data
from the literature regarding the prevention of new subclinical cerebral thromboembolic lesions after PVI.

Secondary objectives:
To assess the impact of PVI on the patient*s neurocognitive status with the AlCath Flux eXtra Gold catheter.
To assess the incidence of peri-procedural serious adverse events of patients for PVI with the AlCath Flux eXtra Gold catheter.
To assess the incidence of post-procedural clinical TE events with the AlCath Flux eXtra Gold.
To assess the acute procedural success rates of PVI with the AlCath Flux eXtra Gold catheter.
To collect procedure and ablation related data regarding PVI with the AlCath Flux eXtra Gold ablation catheter.

To assess the rate of three months success of PVI with the AlCath Flux eXtra Gold ablation catheter.

Study design

International, multicenter, prospective, single arm, pilot study,

Study burden and risks

The associated risk with a PVI ablation is not study specific and not different from risks associated with a standard PVI ablation.
The risks associated with study specific diagnostic procedures MRI, Transoesofagale Echography (TEE) or Intracardiac Echography (ICE - if TEE not possible) and neurological questionaires and tests are described in the protocol section 6.2.
To minimize the risks from these diagnostic procedures, subjects with a contraindication for TEE and/or MRI are excluded from the study. The patient must also give prior written consent if he/she wants to be informed about any additional clinically relevant finding seen on the MRI.
No additional risks are expected from the neurological questionnaires and tests.

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

* sympotomatic paroxysmal atrial fibrillation (AF)
* indication for left atrial ablation for AF according to ESC guidelines
* Anticoagulation according to clinical routine using coumarin derivates with a target INR between 2.0 and 3.0 for at least 3 weeks prior to the scheduled ablation procedure or novel oral anticoagulants (NOACs).
* geographically stable during the study
* patient is willing and able to provide written informed consent

Exclusion criteria

* < 18 years
* Long standing persistent or persistent Atrial Fibrillation
* CHA2DS2-VASc score >= 5
* Prior ischemic stroke or Transient Ischemic Attack
* Previous PV ablation
* Contraindication for antigoagulation therapy
* Contraindication for Diffusion-Weighted MRI
* Claustrophobia
* Contraindication for transesophageal echocardiography (TEE) or intracardiac echography (ICE, if TEE not possible)
* Implanted cardiovascular device
* Acute coronary syndrome < 3 months prior to scheduled ablation
* Moderate to severe valvular heart disease
* LA size > 55 mm
* non-controlled heart failure or current and recent heart failure (< 1 month prior to ablation)
* Ejection fraction < 35%
* Conditions that prevent patient*s participation in neurocognitive assessment
* Female patients who are pregnant or breast feeding
* footnote: ferromagnetic implants without approval for MRI investigations at the respective MRI unit.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2015
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	AlCath Flux eXtra Gold
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-07-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	15-07-2016
Application type:	Amendment
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	NCT02275260
CCMO	NL51329.100.14