Pulmonary Vein Ablation using Irreversible Electroporation - a safety study

Published: 17-04-2019
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Safety and feasibility of IRE for PVI

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

Summary

ID

NL-OMON47967

Source
ToetsingOnline

Brief title
Safety of PVI using IRE

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Abott/ St Jude Medical,St. Jude Medical

Intervention

Keyword: Atrial fibrillation, Catheter ablation, Irreversible electroporation, Pulmonary vein isolation

Outcome measures

Primary outcome

* Acute efficacy: Acute pulmonary vein isolation with entrance and exit block

* Brain MRI: The occurrence of lesions on the DWI/FLAIR MRI will be scored as yes/no and the number of lesions will be stored.

* Esophagoscopy: The occurrence of procedure related lesions, classified as: no lesion, minimal lesion (small erythema/erosion with intact mucosa), severe erythema/erosion and perforation

* Pulmonary vein diameter: The occurrence of pulmonary vein stenosis (> 50 % reduction in diameter) as measured using the pre-CT-scan and post contrast-enhanced MRI.

* Safety of investigational devices: Descriptive statistics will be used, for example counts, means or medians. as appropriate.

Secondary outcome

* Procedure duration

* Fluoroscopy time

* Acute procedure related complications

* Feasibility and accuracy using MEIS during IRE ablation

* Cardiac enzymes levels related to IRE-ablation

* Cardiac function as determined using echocardiography

Study description

Background summary

Atrial fibrillation (AF), the most common cardiac arrhythmia. It is responsible for significant morbidity and mortality in the general population mainly caused by congestive heart failure and ischemic stroke. In case of symptomatic AF, refractory or intolerant to antiarrhythmic medication, catheter ablation treatment may be performed. In catheter ablation treatment, thermal lesions are applied around the pulmonary vein ostia, thereby electrically isolating the PVs from the left atrium. Catheter ablation can be performed using different techniques. Most frequently, point-by-point ablations using radiofrequent (RF) current are applied. Reasonable alternatives include circumferential RF, cryoballoon and laserballoon ablations. Major disadvantages of current therapies are risks of complications (PV stenosis, cerebral ischemia, phrenic nerve palsy, esophageal or coronary damage) and the mediocre success rates, especially after one procedure due to reconnection of the pulmonary veins (up to 50%) and requering a second procedure. To overcome these disadvantages, our research group investigated the potential of using a (low energy) direct current (DC) circumferential ablation technique for cardiac ablation. With DC the injury is not thermal mediated, but caused by a strong electrical field that affects the lipid structure of the cell membrane leading to cell death. This is called irreversible electroporation (IRE). Due to the non-thermal nature of IRE ablation, it may be safer and more effective compared to current techniques. In the pilot study 10/10 patients were treated succesfully and without complications. The multi-electrode impedance system (MEIS) has been developed to measure the level of contact between the catheteter and heart. During this study MEIS will be used to perform measurements to assess the feasibility of this system. The output of MEIS will not be used during the procedure and thus will not influence the procedure.

Study objective

Safety and feasibility of IRE for PVI

Study design

Interventional

Intervention

Pulmonary vein antrum isolation with irreversible electroporation

Study burden and risks

The main difference with standard medical care is the use of the IRE circular ablation catheter and application of IRE instead of RF energy. In addition to standard care, an esophagoscopy and a cerebral and cardiac MRI will be performed the day after the procedure, increasing the burden for participation in comparison with standard care. The pilot study and previous animal studies showed that the risks associated with IRE are low. A total of 10 patients were treated successfully and without complications associated with the IRE procedure during the pilot study. IRE might be more successful than RF ablation. It also may avoid heat induced coagulum formation, cardiac perforation due to tissue overheating, and heat induced PV stenosis.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients age is * 18 years and * 80 years
* Patients must provide written, informed consent
* Patients with paroxysmal or persistent atrial fibrillation. Persistent AF is defined as sustained episodes of atrial fibrillation lasting >7 days.
* Patients undergoing a first-time ablation procedure for atrial fibrillation
* All pulmonary vein diameters at computed tomography or magnetic resonance imaging *26 mm
* AF must be recorded at least once by ECG, holter, telemetry, loop recorder or internal device

Exclusion criteria

* Not capable of giving informed consent
* Patients with longstanding persistent AF, defined as sustained episode lasting >1 year
* Patients with any exclusion criteria or contra-indications for electrophysiologic study and ablation in the LA (under conscious sedation), such as pregnancy or presence of a LA thrombus
* Patients that cannot undergo a contrast enhanced MRI-scan (e.g. implanted devices, renal function or anxiety)
* Patients that cannot undergo an esophagoscopy

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):	10-05-2019
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Irreversible electroporation catheter
Registration:	No

Ethics review

Approved WMO Date:	17-04-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL69129.041.19

Study results

Results posted: 11-08-2022

First publication
11-08-2022