Pulmonary Vein Isolation with Irreversible Electroporation, a pilot study

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Primary Objective: The primary objective of the pilot study is to evaluate the feasibility and acute efficacy of irreversible electroporation for pulmonary vein antrum isolation in patients with atrial fibrillation:- Acute pulmonary vein isolation...

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

Summary

ID

NL-OMON47849

Source
ToetsingOnline

Brief title
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: Ministerie van OC&W,Abbott /St Jude Medical,St. Jude Medical

Intervention

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

Outcome measures

Primary outcome

To assess:

- Acute pulmonary vein isolation with entrance and exit block

- Acute device related complications

Secondary outcome

To assess:

- Maneuverability of IRE catheter in the left atrium

- Positioning of catheter at PV antrum

- Acute procedural complications

- Procedural duration

- Fluoroscopy time

- Feasibility of MEIS contact measurements

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. The IRE catheter has not been tested in humans yet.

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

Primary Objective:
The primary objective of the pilot study is to evaluate the feasibility and acute efficacy of irreversible electroporation for pulmonary vein antrum isolation in patients with atrial fibrillation:

- Acute pulmonary vein isolation with entrance and exit block
- Assess (acute) device related complications

Secondary Objectives:
The secondary objectives of the pilot study are to assess:
- Maneuverability of IRE catheter in the left atrium
- Positioning of catheter at PV antrum
- Procedural duration
- Fluoroscopy time
- Assess (acute) procedural complications
- Feasibility of using MEIS during IRE procedures
- Correctness of MEIS prior to each IRE application

Study design

Feasibility pilot study

Intervention

Pulmonary vein antrum isolation with irreversible electroporation

Study burden and risks

The overall burden and risk for participating patients is thought to be low. The burden associated with participation is the same as standard medical care. The only difference is that in this study ablations are performed with the IRE catheter.

Risks in catheter ablation therapy can be procedural and device related. Some procedural related complications include: vascular complications, pericardial effusion and tamponade. These complications are mainly related to creation of transvenous access and the transseptal puncture. These risks are in IRE ablations comparable to standard medical treatment.

Some device related complications in conventional RF ablations include: TIA, cerebral infarction and pulmonary vein stenosis. In this study, first in man IRE ablations are performed. Multiple porcine studies have shown that in IRE the risk of pulmonary vein stenosis, phrenic nerve palsy, esophageal and coronary damage is very low. Furthermore. IRE also may avoid heat induced coagulum formation. Therefore, the risk on complications is regarded to be very low.
IRE may be more successful in creating permanent pulmonary vein isolation.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
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 drug-refractory, symptomatic 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 * 23 mm
- AF must be recorded at least once by ECG, holter, telemetry, loop recorder or internal device
- Patients have non-valvular AF

Exclusion criteria

- Not capable of giving informed consent
- Prior PVAI with RF or Cryo ablation
- Patients with longstanding persistent AF (defined as sustained episode lasting >1 year)
- One or more PVs with a diameter at computed tomography or magnetic resonance imaging > 23 mm
- Patients with any exclusion criteria or contra-indications for electrophysiologic study and ablation in the LA, such as pregnancy or presence of a LA thrombus

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-11-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	(1) Irreversible electroporation catheter and (2) Multi-Electrode Impedance System (MEIS)
Registration:	No

Ethics review

Approved WMO Date:	29-08-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-11-2018
Application type:	Amendment
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	NL60436.041.17

Study results

Date completed: 20-02-2019

Results posted: 11-08-2022

First publication
14-10-2020