Long-term follow up after second generation cryo balloon ablation in patients with persistent atrial fibrillation: A single centre cohort with 5 years follow up.

Published: 23-03-2018
Last updated: 12-04-2024

The aim of this study is to investigate the acute and long-term efficacy of the second generation CB after with a follow up range of 1-5 years follow up. In a cohort of patients with drug resistance persistent atrium fibrillation.

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

Summary

ID

NL-OMON46403

Source
ToetsingOnline

Brief title
CRYOpers

Condition

- Cardiac arrhythmias

Synonym
recurrence of atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Subsidie wordt gezocht van Stichting Wetenschap OLVG

Intervention

Keyword: Ablation, Cryo balloon, Persistent atrial fibrillation

Outcome measures

Primary outcome

Freedom of recurrence of atrial fibrillation (>30sec documented on ECG, Holter or CIED). Recurrence of AF will be categorized in paroxysmal (if less than 7days), persistent (if between 7days- 1 year) or longstanding persistent (if less than 1year). The occurrence will be categorized in four groups, one or less AF episode a year, 2-3 AF episodes a year, more than 3 AF episodes a year or permanent AF.

Secondary outcome

- Use of anti arrhythmic drugs during the follow up period.

- Freedom of recurrence of any atrial arrhythmia (>30sec documented on ECG, Holter or CIED).

- Quality of life (AFEQT questionnaire).

- Symptoms of palpitations after ablation

- Acute procedural success

- Early complications:

- Groin vascular complication,

- Transient phrenic nerve palsy,

- Pericardial effusion.

- Procedural stroke

- Late complications:

- Persistent phrenic nerve palsy,

- Venous thrombosis,

- 30 days mortality.

- Procedural characteristics; procedure time, fluoroscopic time, total ablation

time, total amount of applications.

- Cryo characteristics; pulmonary veins failed to isolate, average temperature

during application.

Study description

Background summary

Pulmonary veins isolation has become a cornerstone in treatment of atrial fibrillation since several years. Multiple modalities can be used to achieve isolation. With improvement of ablation techniques, the success rate at 1-year increases to 50-75%. No studies have been published that describe the follow up duration beyond 24 months.

Study objective

The aim of this study is to investigate the acute and long-term efficacy of the second generation CB after with a follow up range of 1-5 years follow up. In a cohort of patients with drug resistance persistent atrium fibrillation.

Study design

This is a prospective, single arm, observational cohort study.

Study burden and risks

This studie carries no extra risks for participants.

Contacts

Public
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091AC
NL
Scientific
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091AC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(i) Index pulmonary veins isolation between 2012-2017 (ii) second generation cryo ballon used during pulmonary vein ablation (iii) persistent atrial fibrillation (>7 days, <1 year) as initial indication for ablation

Exclusion criteria

(i) Any left atrium ablation prior to index pulmonary veins isolation (ii) additional ablation lines, except cavotricuspid isthmus line (iii) unwilling/ uncapable to provide informed consent for long term follow up.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2018
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	23-03-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	17-07-2018
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
CCMO	NL63586.100.17