PVAC GOLD versus Irrigated RF single tip Catheter with Contact FORCE Ablation of the Pulmonary Veins for treatment of drug refractory Symptomatic Paroxysmal and Persistent Atrial Fibrillation

Published: 06-03-2015
Last updated: 21-04-2024

We hypothesize that PVAC GOLD is non-inferior to Single Tip catheter ablation with Contact Force sensor guided by 3-D mapping. This will be tested by comparing procedural characteristics and long term outcome with regard to safety, and effectiveness...

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

Summary

ID

NL-OMON47914

Source
ToetsingOnline

Brief title
GOLD-FORCE

Condition

- Cardiac arrhythmias

Synonym
paroxysmal atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ablation, Atrial fibrillation, PVAC, Single Tip

Outcome measures

Primary outcome

Effectiveness: Freedom of AF during 1 yr follow-up

Burden of AF

Safety: Serious Adverse Events during 30 days post-procedure

Secondary outcome

Effectiveness: Symptom reduction, procedure times, findings during redo

procedure

Safety: Serious adverse events during 1 yr follow-up

Study description

Background summary

As ablation is increasingly in demand for invasive treatment of AF, there is a need for new efficient and safe techniques. Multi-electrode ablation may provide such a method. Currently, there are 2 techniques available, with a few cardinal differences. PVAC GOLD is a relatively simple and quick, but does not use high power irrigated RF energy nor 3-D mapping to guide ablation like the more complex Single Tip catheter with Contact Force sensor guided by 3-D mapping. It is unknown whether despite their differences, both systems are as safe and efficient, with similar long term efficacy.

Study objective

We hypothesize that PVAC GOLD is non-inferior to Single Tip catheter ablation with Contact Force sensor guided by 3-D mapping. This will be tested by

comparing procedural characteristics and long term outcome with regard to safety, and effectiveness: curative treatment leading to freedom of AF

Study design

Multicenter randomized clinical trial in patients with AF accepted for PV ablation

Intervention

Group 1: PVI ablation using PVAC GOLD catheter
Group 2: PVI ablation using irrigated Single Tip catheter

Study burden and risks

All patients will undergo ablation according to local protocol.
All pts will receive additional pre-procedure transesophageal echo. All pts will receive two 7-day Holter recordings. Depending on local standards or standardized care (Meetbaar Beter), many pts may receive such follow-up anyway. The added risk of these tests is negligible. The TEE will probably be most demanding, but is performed to exclude intracardiac thrombus.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Symptomatic Atril Fibrillation, refractory to anti-arrhythmic drugs, with a guideline indication for ablation

Exclusion criteria

prior ablation, dilated atria, prior stroke, significant structural disease requiring invasive treatment, valvular repair/replacement

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2015

Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	PVAC GOLD catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-03-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-11-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-06-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-02-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-04-2019
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	NCT02463851
CCMO	NL49603.100.14