Deliver mOre aPplications for more durable Pulmonary vein IsOlation with the Pentaspline Pulsed Field Ablation catheter, the DOPPIO trial

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to determine if freedom of AF may be improved by delivering more, and targeted PFA applications while avoiding side-effects of higher PFA dosing.

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

Summary

ID

NL-OMON57432

Source
ToetsingOnline

Brief title
DOPPIO

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Boston Scientific

Intervention

Keyword: ablation, atrial fibrillation, electroporation, pulmonary vein isolation

Outcome measures

Primary outcome

the primary study parameter for efficacy is the freedom of atrial arrhythmias after the 2-month blanking period up to 12 months after the procedure. The primary safety outcome is the major adverse event rate of the higher dosing versus the standard dosing arm. The primary safety outcome is the major adverse event rate of the higher dosing versus the standard dosing arm.

Secondary outcome

Extent and position of pulmonary vein reconnection during redo procedures required because of recurrence of arrhythmias that constitute an endpoint in the study.

Arrhythmia burden post-procedure in centers that also use photo-phlethysmografic remote-monitoring as standard of care for all their ablation patients.

Study description

Background summary

Pulmonary vein isolation (PVI) by catheter ablation (CA) has become a widely accepted interventional treatment for patients with symptomatic atrial fibrillation (AF) despite anti-arrhythmic drugs (AAD). Classic thermal ablation modalities use radiofrequency energy or cryo-energy to create cardiac tissue lesions. Irreversible electroporation (IRE) using pulsed field energy (PFA) is a novel technology for cardiac tissue ablation. Initial studies have shown favorable outcome data in patients with AF treated by performing PVI. However, freedom of AF so far is not superior to existing thermal ablation and appears

similarly related to suboptimal durability of lesion formation leading to electrical reconnection. In addition, while classic complications of thermal ablation seem to be mostly avoided, new side-effects such as hemolysis have also emerged possibly related to dosing. Thus, the optimal balance between efficacy and safety is not clearly understood at this time

Study objective

to determine if freedom of AF may be improved by delivering more, and targeted PFA applications while avoiding side-effects of higher PFA dosing.

Study design

DOPPIO is single-blinded randomized controlled clinical trial.

Intervention

Patients will undergo the standard catheter ablation procedure in accordance with good clinical practice, performing PVI with the pentaspline PFA system. In the control group PVI will be performed with 4 basket- and 4 flower-shaped applications of the catheter per pulmonary vein, while in the study group 2 olive-, 4 basket-, and 6 flower shaped applications will be delivered for each pulmonary vein. All other procedural steps will be the same between groups.

Study burden and risks

Patients in the study will be exposed to the same low procedural risks as patients that will be treated with PFA outside of the study. Additional risks of participation in the study are considered marginal based on prior publications in patients when more than 32 but fewer than 60 applications were used during a PFA procedure.
The risk of the additional time and manoeuvring of the catheter to perform the extra ablations is considered low (5-10 minutes) in comparison to the average total procedure time (45-60 min)

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

Patients with paroxysmal atrial fibrillation or persistent atrial fibrillation who have undergone no more than 1 cardioversion and are usually in SR, between 18 and 80 years of age, who will be treated with the pentaspline PFA ablation system, have no contraindication to ablation and its associated procedures, and are able to understand and complete the study for a follow-up duration of >12 months

Exclusion criteria

Patients with chronic atrial fibrillation, younger than 18 years of age, with moderate-severe valvular disease, a severely dilated left atrium, heart failure, COPD GOLD 3 or more, moderate to severe OSAS, serious cardiac disease for which a cardiac intervention in the last or next 3 months, anatomical features that make ablation impossible, CVA in the last 6 months, kidney disease with GFR<45 ml/m2/min

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-05-2025
Enrollment:	378
Type:	Anticipated

Medical products/devices used

Generic name:	pentaspline pulsed field ablation system FARAPULSE
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-04-2025
Application type:	First submission
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	NL88354.100.24