The POWER-PLUS study - Very high power ablation in patients with atrial fibrillation scheduled for a first pulmonary vein isolation

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This prospective, randomized, controlled, unblinded, multicenter study aims at comparing procedural time between conventional CLOSE-guided PVI (35W/50W) versus very high power radiofrequency delivery (90W) in AF patients scheduled for a first PVI.

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

Summary

ID

NL-OMON50970

Source
ToetsingOnline

Brief title
The POWER-PLUS study

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: AZ Sint-Jan Brugge-Oostende AV

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atrial fibrillation, Catheter ablation, Radiofrequency

Outcome measures

Primary outcome

• Procedural time

Secondary outcome

• Efficiency: fluoroscopy time, RF ablation time, fluoroscopy dose, first pass

isolation rate

• Efficacy: single procedure freedom from ATA during month 4, 5 and 6 after

index ablation

• Safety: serious adverse events

Study description

Background summary

The QDOT-MICRO* (Biosense Webster Inc., Irvine, CA, USA) is CE-marked for both conventional and for very high power/short duration ablation to treat atrial fibrillation

Study objective

This prospective, randomized, controlled, unblinded, multicenter study aims at comparing procedural time between conventional CLOSE-guided PVI (35W/50W) versus very high power radiofrequency delivery (90W) in AF patients scheduled for a first PVI.

Study design

This is a prospective, randomized, controlled, unblinded, multicentric study.

Intervention

If deemed eligible for and willing to participate in the study, the patient or legal representative must sign the informed consent form prior to study enrolment. Patients will be randomized on a 1:1 ratio to the conventional group (CLOSE-guided PVI with 35/50W RF delivery) or to the very high power short duration RF delivery group (90W).

Study burden and risks

Patients will undergo catheter ablation for atrial fibrillation as clinically indicated. After randomization, one of two ablation energy protocols will be employed using the same access to the heart and the same (CE-marked) materials to apply ablation at the same locations in the heart. Both energy protocols have been evaluated in previous clinical studies and are currently applied by operators in regular clinical practice based on their preference. Patients in the very high power and short duration RF strategy group may have the benefit of a shorter procedure. Patients will be followed after the procedure with Holter monitoring as clinically indicated after ablation.

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

• Age older than 18 years
• Being scheduled for a first PVI only for paroxysmal AF (self-terminating or <7days) or persistent AF (persistent AF is defined as having an AF episode >7d); (patients with paroxysmal AF or short-standing persistent AF presenting with flutter, who are in need of a CTI ablation, are allowed to participate in this trial)
• Patients willing to sign informed consent

Exclusion criteria

• Patients with long-standing persistent AF (long-standing persistent AF is defined as having an AF episode >1yr)
• Previous ablation for AF
• AF secondary to electrolyte imbalance, thyroid disease, or reversible or non-cardiac cause
• Left atrial thrombus. LAA thrombus can be determined by preprocedural imaging: intracardiac echo, CT, TEE or MRI.
• Abnormal echocardiography defined by at least one of the following criteria
o Left ventricular ejection fraction <35%
o LA antero-posterior diameter >50 mm (parasternal long axis view, PLAX), if known
• Cardiac surgery within the previous 90 days.
• Expecting cardiac transplantation or other cardiac surgery within 180 days.
• Coronary PTCA/stenting within the previous 90 days or myocardial infarction within the previous 60 days.
• Documented history of a thromboembolic event within the previous 90 days.
• Women who are pregnant or who plan to become pregnant during the study.
• Acute illness or active infection at time of index procedure
• Advanced renal insufficiency
• Unstable angina
• History of blood clotting or bleeding abnormalities.
• Contraindication to anticoagulation.
• Life expectancy less than 1 year.
• Presence of a condition that precludes vascular access.

• Unwilling or unable to provide informed consent.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-09-2021
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	QDOT Micro Catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-09-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NCT04784013
CCMO	NL77957.058.21

Study results

Date completed: 23-06-2022

Results posted: 02-09-2024

First publication
19-10-2022