Pulsed Field Ablation to Irreversibly Electroporate Tissue and Treat AF (PULSED AF)

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

Summary

ID

NL-OMON55237

Source
ToetsingOnline

Brief title
PULSED AF study

Condition

- Cardiac arrhythmias

Synonym
AF, atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Atrial Fibrillation, Pilot and Pivotal, Pulsed AF system, PVI Ablation

Outcome measures

Primary outcome

Protocol page 33:

Pilot Phase Safety Objective:

Assess the incidence of PFA system-related and PFA procedure-related serious adverse events (SAEs) within 30 days post-ablation.

Pilot Phase Effectiveness Objective:

Assess the acute procedural success of PVI ablation with the PFA system.

Pivotal Phase Primary Safety Objective:

Demonstrate an acceptable safety profile of PVI ablation with the PFA system.

Pivotal Phase Primary Effectiveness Objective:

Demonstrate an acceptable chronic effectiveness of PVI ablation with the PFA system, based on freedom from treatment failure.

Secondary outcome

Protocol page 33, 34:

Secondary Objective

The following secondary objective will be reported separately by paroxysmal AF

and persistent AF:

1. Assess changes in quality of life from baseline through 12 months after the

index ablation

procedure.

Study description

Background summary

protocol page 30 :

Catheter ablation is established as an acceptable line of treatment for patients with recurrent symptomatic atrial fibrillation (both paroxysmal and persistent) who have failed anti-arrhythmic drug therapy

Catheter ablation treatment strategies for AF have evolved over time and currently include pulmonary vein isolation (PVI) as the cornerstone of ablation therapy in all types of AF (paroxysmal and persistent) with several recent studies reporting benefit using a minimal PVI-only type strategy

The Medtronic Pulsed Field Ablation (PFA) system is a novel method of PVI ablation that has the potential to offer a safer and more effective treatment option for AF over existing, approved methods of AF ablation. Medtronic proposes there is a need to investigate PVI ablation with a novel

technology (i.e., PFA system) that is capable of potentially reducing or eliminating collateral
damage, improving lesion formation and durability, and reducing the AF ablation procedure time.

Study objective

Protocol page 33:

The purpose of the study is to provide data demonstrating the safety and effectiveness of the PFA
system for the treatment of atrial fibrillation. The study will also provide first in human insights into
clinical safety and device function of the PFA system for pulmonary vein isolation as a treatment for
AF.

Pilot Phase Safety Objective:
Assess the incidence of PFA system-related and PFA procedure-related serious adverse events
(SAEs) within 30 days post-ablation.

Pilot Phase Effectiveness Objective:
Assess the acute procedural success of PVI ablation with the PFA system.

Pivotal Phase Primary Safety Objective:
Demonstrate an acceptable safety profile of PVI ablation with the PFA system.

Pivotal Phase Primary Effectiveness Objective:
Demonstrate an acceptable chronic effectiveness of PVI ablation with the PFA system, based on
freedom from treatment failure.

Study design

protocol page 36:

The study is a prospective, multi-center, non-randomized, unblinded worldwide pre-market clinical
study. Adult subjects with a history of drug refractory recurrent symptomatic atrial fibrillation (AF)
will undergo ablation of pulmonary veins and confirmation of entrance block and, where assessable,
exit block with the PFA system. Following the index ablation procedure and hospital discharge, all
study subjects from all participating geographies will be followed at 30 days,

3 months, 6 months,
and 12 months, and will be exited from the study at the conclusion of the 12-month follow-up visit
and associated 24-hour Holter

The study consists of a Pilot Phase and a Pivotal Phase. Overall, up to 475 subjects will be enrolled
to ensure there are 20 Pilot Phase subjects, up to 80 Pivotal Phase roll-in cohort subjects, and 315
Pivotal Phase primary analysis cohort subjects treated with the PFA system, and to account for
subjects not treated prior to exit.

Intervention

Protocol page 40:

The Medtronic Pulsed Field Ablation (PFA) system applies bipolar, biphasic pulsed electric fields
through a circular multi-electrode array catheter to perform cardiac tissue ablation through
irreversible electroporation. The system is intended to be used for the treatment of atrial
fibrillation in humans by isolation of the major cardiac veins.

Study burden and risks

Protocol page 37:

The potential benefits related to the use of the PFA system have been determined to outweigh any
potential risks, providing justification to proceed with clinical investigation. Clinical data are needed
to demonstrate that the safety profile and proper lesion creation established in preclinical testing
is confirmed in a clinical setting. Also, as demonstrated in preclinical studies the PFA system
offers potential advantages over existing approved or cleared alternatives such as
reducing/eliminating collateral damage, improving lesion formation and durability, and reducing
the AF ablation procedure time.

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

A diagnosis of recurrent symptomatic paroxysmal or persistent AF with failure of at least one AAD (class I or III) for AF as evidenced by recurrent symptomatic AF, or intolerable side effects due to AAD.

Exclusion criteria

Long-standing persistent AF (continuous AF that is sustained >12 months)
Patient who is not on oral anticoagulation therapy for at least 3 weeks prior to the ablation procedure

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2020
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Pulse Select Pulsed Field Ablation (PFA) system
Registration:	No

Ethics review

Approved WMO Date:	28-01-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-08-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-03-2021
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-02-2022
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	NCT04198701
CCMO	NL71814.100.19