A Prospective Open-Label Single Arm Post Market Clinical Follow-Up Trial of the FARAPULSE Pulsed Field Ablation System in Patients with Paroxysmal Atrial Fibrillation.

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The purpose of the study is to provide ongoing post-market demonstration of the safety and performance of the FARAPULSEPulsed Field Ablation System in the treatment of patients with paroxysmal atrial fibrillation (PAF).

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

Summary

ID

NL-OMON51524

Source
ToetsingOnline

Brief title
FARA-Freedom Trial

Condition

- Cardiac arrhythmias

Synonym
irregular heartbeat, Paroxysmal Atrial Fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: FARAPULSE, Inc
Source(s) of monetary or material Support: the industry

Intervention

Keyword: Ablation System, FARAPULSE, Paroxysmal Atrial Fibrillation

Outcome measures

Primary outcome

The primary safety endpoint is the Composite Safety Endpoint (CSE) defined as

the proportion of Safety Subjects with one or more of the

following device- or procedure-related SAEs as adjudicated by the CEC based on

protocol definitions.

Early onset (within 7 days of an index or Rescheduled Index procedure:

• Death

• Myocardial infarction

• Persistent phrenic nerve palsy

• Stroke

• Transient ischemic attack (TIA)

• Peripheral or organ thromboembolism

• Cardiac tamponade / perforation

• Pericarditis

• Pulmonary edema

• Vascular access complications

• Heart block

• Gastric motility/pyloric spasm disorders

Late onset (any time through the completion of 12 month follow-up visit)

• Pulmonary vein stenosis

• Atrio-esophageal fistula

Secondary outcome

1. Severe Ablation Complications

2. Nonserious / Serious CSEs

3. Post-Blanking Direct Current Cardioversions

4. Post-Blanking Arrhythmia Hospitalizations

5. Any Related SAE

6. Any Related Stroke or TIA

Study description

Background summary

Atrial fibrillation is an irregular and often rapid heart rate that can increase the risk of stroke, heart failure and other heart-related complications. During atrial fibrillation, the heart's two upper chambers (the atria) beat chaotically and irregularly * out of coordination with the two lower chambers (the ventricles) of the heart.

The first line of treatment is typically drug therapy and direct current cardioversion (DCCV). DCCV is a medical procedure to convert an abnormal heart rate back to normal rhythm using electricity and/or drugs. As a reasonable alternative to restoring sinus rhythm via long-term pharmacologic therapy, catheter ablation is being performed with greater frequency. Cardiac ablation is a procedure that is used to scar small areas in your heart that may be involved in your heart rhythm problems. This can prevent the abnormal electrical signals or rhythms from moving through the heart.

The FARAPULSE* Pulsed Field Ablation System places a catheter in the pulmonary

veins connected to your heart and delivers pulsed electric energy to the veins where the misfiring in your heart first starts. This study ablation device will be delivered through a puncture to the femoral vein in your leg. FARAPULSE is conducting a post market clinical study to evaluate whether this ablation procedure improves heart rhythm.

Study objective

The purpose of the study is to provide ongoing post-market demonstration of the safety and performance of the FARAPULSE
Pulsed Field Ablation System in the treatment of patients with paroxysmal atrial fibrillation (PAF).

Study design

Subjects will undergo percutaneous endocardial ablation for pulmonary vein isolation using the FARAPULSE Pulsed Field Ablation System. Subjects with typical right-sided (isthmus-dependent) atrial flutter (AFL) may undergo ablative interruption of the cavo-tricuspid isthmus (CTI).
Class I/III antiarrhythmic drugs (AADs) will be discontinued at Day 60 ± 10, subject to investigator discretion.
Subjects will then be followed at 7 days, 30 days, 90 days, 6 months, and 12 months for adverse events (AEs).
Subjects will be monitored with weekly scheduled plus symptom-driven event monitoring, as well as 6 and 12-month Holter monitoring, for freedom from recurrent arrhythmia AF, AFL or atrial tachycardia) after the Blanking Period (Days 0 - 90).

Several analysis populations are defined for this study, including:
- Safety subjects
- Modified intent-to-treat (mITT) subjects
- Per Protocol (PP) subjects

Study burden and risks

Subject*s participation in this study will last 13 months and consists of a screening period, treatment period and a follow-up period.

The following is not Standard of Care:
Study Consent form to be signed.
The use of event monitor
Quality of life questionnaires (EQ-5D-3L & AFEQT) to be filled in at 2 visits
Follow-up visits phone call
TEE/ICE (is SoC in UMCG, not in Catherina hospital & OLVG)
CT (only UMCG)
The duration of use holter, 72h

Risks associated: Participation in the study carries additional assessments and imaging above the standard of care.
All other study-specific assessments are clinic and physical assessments that would be within the range of standard follow-up of patients with a this medical history.
An additional risk of participating in a clinical study is the risk of a lapse of confidentiality or exposure of personal identifying information.

Risk-benefit analysis; The risk involved in the clinical study is minimized due to the fact the device being used is CE-marked and the study design falls within the intended use population. Subjects can still receive the same device treatment outside of the study. The risk of participating in the study is only minimally increased as compared to receiving the device outside the study, as there is a higher degree of imaging and clinical assessment than would be present otherwise. Additionally, there are the risks involved in data collection. These risks, though, have been mitigated by the benefit of additional clinical follow-up and closer care, as well as procedures which have been put in place to protect subjects* personal information.

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

Study subjects are required to meet all the following inclusion criteria to participate in this study:
1. Patients with PAF that meets all the following criteria:
a. Paroxysmal: AF that terminates spontaneously or with intervention within 7 days of onset.
b. Frequency:
i. Physician documentation of recurrent PAF (two or more episodes) within 6 months, AND
ii. At least one (1) documented episode by an approved recording device within 12 months of enrollment.
c. Drug Failed atrial fibrillation drug (AAD) treatment, meaning therapeutic failure of at least one AAD (class I - IV) for efficacy and / or intolerance.
2.Patients who are >= 18 and <= 80 years of age on the day of enrollment.
3. Patient participation requirements:
a. Is willing and capable of providing Informed Consent to undergo study procedures.
b. Is willing to participate in all examinations and follow-up visits and tests associated with this clinical study.

Exclusion criteria

Subjects will be excluded from participating in this study if they meet any one of the following exclusion criteria:
1. Atrial fibrillation that is any of the following:
a. Persistent (both early and longstanding) by diagnosis or continuous duration > 7 days
b. Secondary to electrolyte imbalance, thyroid disease, alcohol or other reversible / non-cardiac causes
c. Requires four (4) or more direct-current cardioversions in the preceding 12 months
2. Any of the following atrial conditions:
a. Left atrial anteroposterior diameter >= 5.5 cm
b. Any prior atrial endocardial or epicardial ablation procedure, other than right sided cavotricuspid isthmus ablation or for right sided SVT
c. Any prior atrial surgery
d. Interatrial septal patch or interatrial shunt

e. Atrial myxoma
f. Current LA thrombus
g. LA appendage closure, device or occlusion
h. Any PV abnormality, stenosis or stenting (common and middle PVs are admissible)
3. At any time, one or more of the following cardiovascular procedures, implants or conditions:
a. Sustained ventricular tachycardia or any ventricular fibrillation
b. Hemodynamically significant valvular disease
c. Clinically significant hypertrophic cardiomyopathy
d. Any prosthetic heart valve, ring or repair including balloon aortic valvuloplasty
e. Contraindication to femoral venous access
4. Any of the following procedures, implants or conditions:
a. At baseline:
i. Congestive heart failure with New York Heart Association (NYHA) Class III or IV
ii. Left ventricular ejection fraction (LVEF) < 35%
iii. Uncontrolled hypertension (SBP > 160 mmHg or DBP > 95 mmHg on two BP measurements at baseline assessment)
iv. Implantable loop recorder or insertable cardiac monitor
b. Within the 3 months preceding the Consent Date:
i. Myocardial infarction
ii. Unstable angina
iii. Percutaneous coronary intervention
iv. Implantation of a pacemaker, cardioverter defibrillator or cardiac resynchronization therapy device
v. Heart failure hospitalization
vi. Treatment with amiodarone
vii. Pericarditis or symptomatic pericardial effusion
viii. Gastrointestinal bleeding
c. Within the 6 months preceding the Consent Date:
i. Heart surgery
ii. Stroke, TIA or intracranial bleeding
iii. Any thromboembolic event
iv. Carotid stenting or endarterectomy
5. Diagnosed disorder of blood clotting or bleeding diathesis
6. Contraindication to, or unwillingness to use, systemic anticoagulation
7. Patient who is not on anticoagulation therapy for at least 3 weeks prior to the ablation procedure
8. Women of childbearing potential who are pregnant, lactating, not using birth control or planning to become pregnant during the anticipated study period
9. Medical conditions that would prevent participation in the study, interfere with assessment or therapy, significantly raise the risk of study participation, or confound data or its interpretation, including but not limited to:
a. Body mass index (BMI) > 45.0

b. Solid organ or hematologic transplant, or currently being evaluated for an organ transplant
c. Severe lung disease, pulmonary hypertension, or any lung disease associated with chronic abnormal blood gases or requiring supplemental oxygen
d. Renal insufficiency with an estimated glomerular filtration rate (eGFR) < 30 mL/min/1.73 m
or any history of renal dialysis or renal transplant
e. Active malignancy or history of treated malignancy within 24 months of enrollment (other than cutaneous basal cell or squamous cell carcinoma)
f. Active systemic infection
g. COVID-19 disease
I. Current confirmed, active COVID-19 disease
II. Current positive test for SARS-CoV-2
III. Confirmed COVID-19 disease not clinically resolved at least 3 months prior to the Consent Date
h. Other uncontrolled medical conditions that may modify device effect or increase risk, including uncontrolled diabetes mellitus, untreated sleep apnea or active alcohol abuse
i. Predicted life expectancy less than one (1) year
10. Clinically significant psychological condition that in the investigator*s opinion would prohibit the subject's ability to meet the protocol requirements.
11. Current or anticipated enrollment in any other clinical study.
(data collection for registries or retrospective studies is permitted)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-06-2022
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Pulsed Field Ablation System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-04-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-07-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-04-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NCT05072964
CCMO	NL80016.042.21