Complex fractionated atrial electrocardiograms (CFAEs) guided ablation versus pulmonary vein isolation guided ablation in persistent atrial fibrillation, a multicenter randomized trial

Published: 11-01-2016
Last updated: 08-02-2025

to compare the efficacy and safety of complex fractionated atrial electrocardiograms (CFAEs) guided ablation to pulmonary vein isolation based ablation in patients with persistent atrial fibrillation (AF).

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

Summary

ID

NL-OMON53040

Source
ToetsingOnline

Brief title
CIPA

Condition

- Cardiac arrhythmias

Synonym
AF, Atrial fibrillation

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Biosence Webster,Maatschap cardiologie Isala

Intervention

Keyword: Complex fractionated atrial electrocardiograms, persistent atrial fibrillation, pulmonary vein ablation

Outcome measures

Primary outcome

Freedom from recorded atrial fibrillation or atrial flutter or atrial

tachycardia recurrences (>30 seconds) without the use of AADs through 18 months

follow-up, post-blanking, on either a 12 lead ECG on visits or on 24 hour

holter monitoring or on symptom-driven event monitoring.

Secondary outcome

• Freedom from recorded atrial fibrillation or atrial flutter or atrial

tachycardia recurrences (>30 seconds) through 18 months follow-up on

either a 12 lead ECG on visits or on 24 hour holter monitoring or on

symptom-driven event monitoring, regardless of antiarrhythmic drugs

• Freedom from recorded atrial fibrillation or atrial flutter recurrences (>30

seconds) through 18 months follow-up on either a 12 lead ECG on

visits or on 24 hour holter monitoring or on symptom-driven event

monitoring, regardless of antiarrhythmic drugs

• Freedom from recorded atrial fibrillation or atrial flutter or atrial

tachycardia recurrences (>30 seconds) through 18 months follow-up on

either a 12 lead ECG on visits or on 24 hour holter monitoring or on symptom-driven event monitoring, without a new AAD or a previously failed AAD at a greater than the highest ineffective historical dose

• Freedom from recorded atrial fibrillation (>30 seconds) through 18 months follow-up on either a 12 lead ECG on visits or on 24 hour holter monitoring or on symptom-driven event monitoring, regardless of antiarrhythmic drugs

• Clinical/partial success at 18 months regardless of antiarrhythmic drug use, defined as a 75% or greater reduction in the number of AF episodes and/or the duration of AF episodes, or the % time a patient is in AF as assessed with a device capable of measuring AF burden.

• Time to first symptomatic, recorded AF recurrence

• Time to first electrocardioversion

• Symptoms associated with atrial arrhythmias

• Decreased anti-arrhythmic and/or anticoagulant drug requirements

• Quality of life at 6 and 12 months compared to baseline

• Number of redo-procedures

• Total time of fluoroscopy

• Total procedure time (minutes from introduction of first catheter to withdrawal of last catheter)

• Total ablation time

Study description

Background summary

Pulmonary vein isolation (PVI) is a class I indication for drug refractory, symptomatic, paroxysmal atrial fibrillation.2 PVI however, is considered to be not enough for treatment of persistent AF.1,3 To improve the clinical outcome in patients with persistent AF, extensive ablation, including wide antral pulmonary vein isolation and/or multiple linear lesions and/or ablation of complex fractionated atrial electrograms (CFAEs) has been adopted.2-12 Various randomized trials used CFAEs as an additional after PVI, but the results of Nademanee (87% of patients in sinus rhythm after 2.3 years) could not be reproduced.13-16 Nevertheless, in these studies and in a meta-analysis CFAE ablation on top of PVI did improve atrial fibrillation free survival in persistent atrial fibrillation patients (47% to 62%).13-17 As in the study of Nademanee, another study using primarily a CFAE ablation strategy, not on top of pulmonary vein isolation, reported a 82% atrial fibrillation free survival.18 However, in persistent atrial fibrillation, a strategy using CFAE ablation until AF termination during ablation, as primary ablation was never compared to a PVI based strategy.

Study objective

to compare the efficacy and safety of complex fractionated atrial electrocardiograms (CFAEs) guided ablation to pulmonary vein isolation based ablation in patients with persistent atrial fibrillation (AF).

Study design

A prospective, multicenter, randomized unblinded clinical study

Eligible patients who sign the study informed consent form will be randomized into one of two study arms:
• CFAE guided ablation: CFAE mapping and ablation during AF aimed at restoring sinus rhythm during ablation, according to methods by Nademanee9. PVI will be checked before and after ablation using a mapping catheter
• PVI guided ablation: wide antral pulmonary vein isolation during mapping catheter control of pulmonary vein signals

Intervention

CFAE guided ablation
PVI guided ablation

Study burden and risks

Participating patients will not have extra risks
The extra load for the patient will be to fill the quality of live questionares during the study
It is not expected that the patients will have any benifit by participating in the trial

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

1. Patients with persistent atrial fibrillation, defined as atrial fibrillation which is:
a. Sustained beyond 7 days but no more than one year
b. Or lasting less than 7 days, but longer than 48 hours and necessitating pharmacologic or electrical cardioversion
2. Documentation of atrial fibrillation on either a 12-lead ECG or transtelephonic monitoring (TTM), or ambulatory holter monitoring or telemetry strip and a physician*s note showing continuous AF.
3. Failure of at least one antiarrhythmic drug (AAD) (Class I or III) as evidenced by recurrent symptomatic AF or intolerable side effects of the AAD.

Exclusion criteria

1. Continuous AF > 12 months (1-Year) (Longstanding Persistent AF)
1. Previous surgical or catheter ablation for atrial fibrillation
2. Any cardiac surgery within the past 2 months (60 days) (includes PCI)
3. CABG surgery within the past 6 months (180 days)
4. Subjects that have ever undergone valvular cardiac surgical procedure
5. Cardioversion refractory (the inability to restore sinus rhythm for 30 secs or longer following electrical cardioversion).
6. Documented LA thrombus on imaging
7. LA size >50 mm
8. LVEF < 30%

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-05-2016

Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	11-01-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-01-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-05-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-03-2022
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	31-03-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-01-2025
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
CCMO	NL54589.075.15