Serial hybrid atrial fibrillation ablation

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To assess if serial hybrid ablation for freedom of AF is superior to epicardial ablation alone in patients with (long-standing) persistent AF

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

Summary

ID

NL-OMON41273

Source
ToetsingOnline

Brief title
SHAFT

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Hartcentrum Twente

Intervention

Keyword: Ablation, Atrial fibrillation, Hybrid, PVI

Outcome measures

Primary outcome

Serial hybrid ablation for freedom of AF (AF episode lasting more than 5 minutes or overall burden >0.5% of time spent in AF on a monthly basis) after a follow-up of 12 months is superior to epicardial ablation alone in patients with (long-standing) persistent AF.

Secondary outcome

the number of pulmonary veins needing re-isolation by the EP during the endocardial intervention. The percentage of cross-over from the surgical arm to surgery and serial hybrid ablation, after patients have reached the primary endpoint AF. The occurence of atrial ectopy (monomorphic and multiform atrial extrasystoles) even during the blanking. Number of complications and thrombo-embolic events in both groups. Necessity of antiarrhythmic drugs to maintain sinus rhythm. Burden of AF in both groups if AF is still present.

Study description

Background summary

Treatment of (long-standing) persistent atrial fibrillation (AF) remains cumbersome and the surgical (epicardial) approach seems to be the most effective. Still, however a significant amount of failures exist which is mostly due to incompleteness of the surgical ablation lines. Checking, and if necessary additional ablation, of these lines afterwards endocardially by the cardiologist (the so-called serial hybrid approach) could overcome this problem.

Study objective

To assess if serial hybrid ablation for freedom of AF is superior to epicardial

ablation alone in patients with (long-standing) persistent AF

Study design

The study is designed as a prospective single centre randomized study, with a follow-up of 1 year

Intervention

Patients will undergo a standardized surgical epicardial ablation for atrial fibrillation and will subsequently be randomized for a second endocardial intervention by the cardiologist/electrophysiologist (EP) after 6-8 weeks versus regular follow-up.

Study burden and risks

If randomized to the serial hybrid arm patients will undergo a second procedure performed by the EP. This is the regular procedure as also performed for patients with (paroxysmal) atrial fibrillation and is done under complete anesthesia. Risks for this procedure include the following (but not exclusive) complications: 1) venous access related complications (hematoma, AV fistula): 1-3% 2) cardiac perforation with or without tamponade : <1% and 3) thrombo-embolic events notably cerebro-vascular accidents: <1%. Patients need to stay in the hospital for 1 night after the procedure and after discharge do not have a recovery phase. Follow-up of these patients to assess successfulness of the procedure consists of 5 outpatient visits which are one more than for the regular procedure.

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

All patients screened are accepted for pulmonary vein isolation according to the current guidelines.
1) candidates for enrolment should have long standing persistent or persistent AF as defined in the guidelines for which they received at least one cardioversion with EHRA class * II
2) Furthermore, on echocardiogram left atrial size needs to be more than >46 mm on long axis or >35 cc/m2.

Exclusion criteria

1) Significant coronary artery disease has to be excluded as a trigger for AF by means of cardiac CT, if necessary a coronary angiogram will be performed.
2) Previous pulmonary vein isolation (epicardial or endocardial) or cardiac surgery. 3) Significant valvular disease present on echo (mitral or aortic valve regurgitation above grade 2, moderate to severe mitral or aortic stenosis). 4) Concomitant cardiac surgery needed 5) left ventricular ejection fraction <40% 6) hypertrophic (obstructive) cardiomyopathy or dilated cardiomyopathy defined as an ejection fraction < 40% 7) active infection or sepsis 8) pregnancy 9) myocardial infarction within the previous 3 months 10) AF secondary to electrolyte imbalance, thyroid disease, other reversible or noncardiovascular causes for AF 11) known sensitivity to heparin or warfarin 12) life expectancy of <12 months 13) pleural adhesions 14) prior thoracotomy 15) patients on dialysis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2014
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	30-03-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NCT01582828
CCMO	NL42236.044.12