Thoracoscopic surgical versus catheter ablation approaches for primary treatment of persistent atrial fibrillation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24028

Source
Nationaal Trial Register

Brief title
APPROACH AF

Health condition

Atrial fibrillation

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Absence of any atrial tachyarrhythmia without the use of antiarrhythmic drugs once a total number of 72 patients with AF recurrences after a single procedure have been reached

Secondary outcome

- Freedom of arrhythmia with or without AAD after a single procedure after one year
- Freedom of arrhythmia after 12 months with or without AAD after both procedures
- Freedom of arrhythmia after 5 years
- Cost-effectiveness of both procedures in isolation, and the combination of both procedures
- Quality of life

Study description

Background summary

Catheter ablation, endocardial pulmonary vein isolation (PVI) in particular, is the most commonly applied approach to treat drug refractory AF. However, in patients with persistent AF, results are modest. Alternatively, the PVs can be approached epicardially by thoracoscopic surgery to isolate the PVs. This approach is more efficacious, at the cost of a more invasive procedure and longer hospital stay. However, no studies have been conducted comparing catheter with thoracoscopic ablation in patients with persistent AF as a primary invasive procedure after failing treatment with anti-arrhythmic medication.

Study objective

This current study aims to assess a patient specific therapy plan for patients with persistent AF by randomizing thoracoscopic versus catheter ablation for PVI without adjuvant substrate ablation

Study design

-

Intervention

Thoracoscopic surgical PVI versus catheter PVI

Contacts

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Eligibility criteria

Inclusion criteria

- Age is between 18 and 80 years.
- Persistent AF as defined following the ESC 2016 Guidelines, evidenced by 1) ongoing AF on the ECG or 2) documentation of AF necessitating cardioversion.
- AF documented by ECG or Holter < 1 year ago.
- At least one class I or III anti-arrhythmic drug in standard dosage has failed or is not tolerated.
- Left atrial volume index ≤ 45 ml/m2
- Legally competent and willing to sign the informed consent.
- Willing and able to adhere to the follow-up visit protocol.
- Life expectancy of at least 2 years.

Exclusion criteria

- Prior intervention (catheter ablation or minimally-invasive thoracoscopic ablation) for AF.
- AF is secondary to electrolyte imbalance, thyroid disease or other reversible or non-cardiovascular causes.
- Documentation of CTI dependent atrial flutter
- Valvular AF
- Paroxysmal AF
- Long standing Persistent AF, defined as AF continuously present for longer than 1 year.
- Body mass index >35kg/m2
- NYHA class IV heart failure symptoms or left ventricular ejection fraction <35%.
- NYHA class III heart failure symptoms, unless caused or aggravated by AF.
- Myocardial infarction within the preceding 2 months.
- Active infection or sepsis (as evidenced by increased white blood cell count, elevated CRP level or fever >38,5 °C).
- Known and documented carotid stenosis > 80%
- Planned cardiac surgery for other purposes than AF.
- Pregnancy or child bearing potential without adequate anticonception.
- Requirement of anti-arrhythmic drugs for ventricular arrhythmias.
- Presence of intracardiac mass or thrombus (discovery of any thrombus or intracardiac mass after signing of the informed consent will result in withdrawal of the subject from the study)

- Co-morbid condition that possesses undue risk of general anesthesia or port access cardiac surgery (in the opinion of the operator).
- History of previous radiation therapy on the thorax
- Circumstances that prevent follow-up
- No vascular access for catheterization.
- History of previous thoracotomy.
- Factors precluding transseptal puncture for catheterization. Sample size

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-09-2019
Enrollment:	170
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-11-2019
Application type:	First submission

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
NTR-new	NL8153
Other	METC AMC : 2018_279

Study results