Atrial Fibrillation Ablation and Autonomic Modulation via Thoracoscopic Surgery, 10 year follow up.

Published: 06-01-2025
Last updated: 18-01-2025

Primary Objective:The study aims to assess freedom from AF ten years after the procedure without the use of antiarrhythmic drugs in patients who underwent thoracoscopic ablation in advanced AF with or without GP ablation. Secondary Objectives:1. To...

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

Summary

ID

NL-OMON57228

Source
ToetsingOnline

Brief title
AFACT-10

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
afib, Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ablation, Atrial Fibrillation, Autonomic, Ganglia, Thoracoscopy

Outcome measures

Primary outcome

Main study parameter/endpoint:

The primary endpoint of the study is freedom of AF after ten years after the procedure without the use of antiarrhythmic drugs. Freedom of AF is defined as the absence of documentation of episodes of AF, atrial flutter or atrial tachycardia >30 seconds on all holters and ECG recordings during follow up.

Secondary outcome

Secondary study parameters/endpoints:

- Classification of AF recurrence (paroxysmal, persistent, permanent AF, and atrial tachycardia).

- Left Atrial (LA) Volume and Function 8 to 10 years post procedure

- Difference in Quality of Life from baseline to ten years post-procedure in points

- Number and reasons for pacemaker implants during the ten-year follow-up period.

- Number and reasons for additional ablation procedures during the ten-year follow-up period.

- Occurrence of major adverse events (heart failure, stroke, major bleeding, mortality) during the follow-up period.

- Causes of death during the ten year follow-up.

- Freedom of AF with AADs, defined as the absence of documentation of episodes

of AF, atrial flutter or atrial tachycardia >30 seconds since start of the last

dose of AAD, measured at the time of data collection 10 years safter the

procedure.

Study description

Background summary

Atrial Fibrillation (AF) is the most common cardiac arrhythmia. Treatment of AF is challenging, despite increasing pharmacological and technological treatment options. Despite state-of-the-art pharmacological therapies targeting the ventricular rate or aiming to restore sinus rhythm (SR), many patients with AF stay symptomatic. Pulmonary vein isolation (PVI) through catheter or surgical ablation has become the primary treatment modality for individuals necessitating invasive intervention. PVI has shown favorable outcomes, particularly in cases of paroxysmal AF. However, its efficacy in advanced AF, encompassing persistent AF, enlarged left atria, or previous unsuccessful ablations, remains limited, with a reported freedom from AF at one year after surgical ablation of 69% in persistent AF cases.

In pursuit of enhancing treatment efficacy, various strategies have been advocated, including partial atrial denervation through ablation of the major autonomic ganglion plexus (GP). The autonomous nervous system, especially the GPs, plays an important role in initiating AF. Activity of the GP, characterized by both parasympathetic and sympathetic stimulation, has been implicated in AF induction through mechanisms involving triggered firing and early afterdepolarizations.

However, the AFACT trial, a large RCT in minimally invasive AF surgery patients, examined the efficacy of GP ablation in patients with advanced AF and found no reduction in AF recurrence up to one and two years. To the contrary, it revealed an elevated incidence of major procedural complications, including bleeds necessitating procedure termination or sternotomy, as well as an increased need for pacemaker implantations due to sinus node dysfunction and AV block.

Long-term follow-up data on GP ablation for AF remain sparse. An observational study examining the seven year outcomes of GP ablation in addition to thoracoscopic PVI compared to PVI alone in a group of permanent AF patients, demonstrated decreasing success rates over time in both groups. Remarkably, the addition of GP ablation to the maze procedure exhibited a significantly lower rate of AF recurrence over a prolonged period exceeding seven years.

Similarly, long-term follow-up data on minimally invasive thoracoscopic AF ablation without GP ablation remain sparse. A recent retrospective cohort study evaluated AF recurrence at 10 years after the procedure, finding that only 42% of a cohort of 22 persistent AF patient were in sinus rhythm, while 58% experienced a recurrence of AF. Despite the high recurrence rate, the study noted an improvement in the quality of life compared to pre-procedure levels. While these findings address crucial issues, several key questions remain unanswered. The study focused on the presence of AF at the 10-year mark rather than freedom from AF over the decade, leaving the question of long term freedom from AF after thoracoscopic AF ablation unresolved. Additionally, the retrospective nature and small cohort size further limit the generalizability of the results.

Currently, There are no data available on long-term efficacy and safety of GP ablation versus no GP ablation. Furthermore, long-term follow-up data in thoracoscopic AF ablation in general are very limited. The potential benefits of GP ablation might become more apparent over extended periods, highlighting the need for further investigation into its long-term efficacy and safety profiles.

Study objective

Primary Objective:
The study aims to assess freedom from AF ten years after the procedure without the use of antiarrhythmic drugs in patients who underwent thoracoscopic ablation in advanced AF with or without GP ablation.

Secondary Objectives:
1. To assess the progression of AF from paroxysmal to persistent or from persistent to permanent over the ten-year follow-up period.
2. To evaluate changes in left atrial volume and function ten years following the procedure.
3. To assess the quality of life of patients ten years after the procedure.
4. To assess the number and underlying reasons for pacemaker implants between the two study arms during the ten-year follow-up period.
5. To evaluate the frequency and reasons for additional ablation procedures during the ten-year follow-up period.
6. To determine the incidence of major adverse events such as heart failure, stroke, major bleeding, and mortality during the follow-up period.
7. To determine and compare the causes of death during the ten year follow-up.
8. To assess freedom of AF since initiation of the last dose of AAD.

Study design

Participants in the AFACT trial will be included in this study, which consists of three parts: an examination of the national mortality database (BRP/NRO), a

prospective cohort study, and a retrospective chart review.

National database examination
Given the age of the population involved, a significant proportion may have deceased since the initial trial. To prevent distress to relatives that could arise from attempting to communicate with deceased individuals, we will cross-reference the national mortality database to identify deceased participants.

Prospective cohort study
Participants of the AFACT trial will be sent a patient information folder. These patients will be invited to the outpatient clinic to sign informed consent. Subsequently, participants will be assessed during a single visit with an investigator. Alongside the clinic visit, patients will receive a 12-lead electrocardiogram (ECG), a 24-hour Holter ECG, a transthoracic echocardiogram (TTE), and a laboratory assessment. If a recent (within the last two years) Holter ECG, TTE or laboratory investigation with the required measurements is available, the investigation will not be repeated. Patients will also be requested to complete an SF-36 quality of life questionnaire. Any abnormalities identified during the clinic visit or diagnostic investigations will be promptly reviewed by a cardiologist, and patients will be referred for further evaluation as deemed necessary.

Retrospective chart review
In the retrospective chart review phase, we will review the medical charts of study participants to gather clinical event data from the years between the AFACT trial procedure and the present. We will combine data obtained from medical chart reviews of the Amsterdam UMC and all other hospitals that the patient attended in AF during the last ten years.
Data collection will include all available electrocardiograms (ECGs) and Holter ECGs obtained during the follow-up period of approximately ten years, documenting occurrences of atrial fibrillation (AF), atrial flutter, and atrial tachycardia. We will specifically attempt to obtain the first documented recurrences of AF since the AFACT study so between 2 and 10 years follow up. Additionally echocardiograms and laboratory assessments from the previous two years will be collected. Furthermore, we will screen for incidences of major cardiovascular adverse events, in particular strokes, bleeding, myocardial infarctions and hearth failure hospitalizations. The general practitioners of the included patients will be asked for additional data sources, such as hospital admissions previously unknown to the researchers.

Study burden and risks

Burden:
- Discomfort of measurements: participants may experience discomfort from the Holter monitoring and venipuncture.
-Time commitment: Participating in the research requires additional time from

the participant.
-Incidental findings: It is possible that incidental findings may be discovered during the examinations that are not directly relevant to the research but may be important for the participant's health.

Risks:
-Venipuncture for Laboratory Investigation:
Minimal Risks: The procedure carries minimal risks, primarily hematoma and prolonged bleeding.
Risk Mitigation: This is one of the most common invasive procedures in medicine and serious complications are rare. The risk of complication is minimized by ensuring the procedure is performed by licensed medical practitioners according to local standards.
-Echocardiography and Rhythm Monitoring:
Risk-Free: These diagnostic procedures are non-invasive and carry no risks.

Benefits:
- Additional Control Visit: Patients receive an extra control visit dedicated to investigating cardiac abnormalities and conducting physical examination. This enhances monitoring and early detection of potential issues.

Overall, the procedures involved in this study carry minimal risks to the participants, are conducted by trained and licensed professionals, adhering to local standards to ensure patient safety and minimize any potential risks.

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

Participant AFACT-trial, comprising of patients who had advanced AF and were randomized to thoracoscopic pulmonary vein isolation for AF with or without aditional epicardial ganglion plexus ablation.

Exclusion criteria

Refusal to be contacted for future studies

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2024
Enrollment:	236
Type:	Anticipated

Ethics review

Approved WMO Date:	06-01-2025
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL87358.018.24