AtRial fibrillation ablation to prevent disease progression of AF-induced atrial Cardiomyopathy in womEn and men

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

Summary

ID

NL-OMON56762

Source
ToetsingOnline

Brief title
RACE X

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: AF ablation, Atrial cardiomyopathy, Atrial fibrillation

Outcome measures

Primary outcome

To determine whether AF ablation compared to pharmacological rhythm management in ACMP patients with AF reduces the incidence of the composite primary endpoint of CV death and first CV hospitalization/urgent visit.

Secondary outcome

To determine whether AF ablation compared to pharmacological rhythm management in ACMP patients with AF reduces:

1. ACMP progression or regression (as measured by LAVI increase or decrease)

2. ACMP associated outcomes including:

a. Hospitalisations/urgent visits for AF/AFL/AT recurrence

b. Hospitalisations/urgent visits for HF

c. Hospitalisations/urgent visits for ischemic stroke (including transient ischemic attack (TIA))

d. Cardiovascular death

3. All-cause mortality

4. Repeated hospitalisations/urgent visits for ACMP associated outcomes

5. Symptoms and improve QoL (measured by EHRA-score, AFEQT and EQ-5D-5L)

6. Healthcare costs

Study description

Background summary

It is hypothesised that the stage of atrial cardiomyopathy (ACMP) and the timing of ablation for atrial fibrillation (AF) may have an impact on the occurrence of ACMP-associated adverse outcomes in patients with AF, including AF recurrences, ischemic stroke, and heart failure (HF) with preserved, mildly reduced and reduced left-ventricular ejection fraction. ACMP results into an atrial substrate being less responsive to rhythm control (including AF ablation) and leading to higher AF recurrence rates and AF progression. Since AF begets AF by advancing the ACMP, early intervention with rhythm control therapies, particularly AF ablation, has shown promise in interrupting ACMP advancement and AF progression. However, existing studies do not specifically explore ACMP's role and the potential of AF ablation in slowing down ACMP progression and ACMP associated outcomes. The RACE X trial aims to fill this gap by randomizing ACMP patients with AF to AF ablation or pharmacological rhythm management (rate and/or rhythm control), providing evidence on ACMP's importance in treatment and prognosis, and reduce hospitalizations/urgent visits for cardiovascular (CV) reasons and CV mortality of patients with AF.

Study objective

The primary objective is to study whether AF ablation, as opposed to pharmacological rhythm management (rate and/or rhythm control according to ESC guidelines), can reduce the incidence of the composite primary endpoint of CV death and CV hospitalisation/urgent visits in patients diagnosed with ACMP and AF. The secondary objectives are ACMP progression as measured by LAVI increase, ACMP associated outcomes (hospitalisations/urgent visits for AF, HF, ischemic stroke, and cardiovascular death), all-cause mortality, repeated hospitalisations/urgent visits for ACMP related outcomes, AF symptoms, quality of life (QoL) and healthcare costs. The exploratory objectives include ACMP progression as measured by additional transthoracic echocardiogram (TTE) measurements, extended ECG (extECG), MRI (subset), CT (subset), circulating biomarkers (Cardiolines subset), and electrophysiological mapping (subset).

Study design

The RACE X trial is a prospective, multicentre, randomized, open-label, blinded-endpoint, superiority, parallel arm, phase IIIb trial. Patients with ACMP and AF are randomized to either receive rhythm control through AF ablation or pharmacological rhythm management in addition to anticoagulation (if indicated) and treatment of comorbidities. Follow-up assessments will be conducted using questionnaires and data from routine clinical care. The trial will take place in 15 participating hospitals in the Netherlands. Patients that are not eligible because of not fulfilling the ACMP inclusion criterion (left atrial volume index (LAVI) >34 ml/m2), but do undergo AF ablation, will be enrolled in a parallel observational RACE X registry and information on

occurrence of CV death and CV hospitalization/urgent visits is collected, in collaboration with the Netherlands Heart Registration (NHR). In the RACE X registry, management of AF is led to the discretion of the treating physician.

Intervention

Patients will then be randomly assigned in a 1:1 ratio, stratified by sex and type of AF (paroxysmal or persistent), to either AF ablation or pharmacological rhythm management (being rate or rhythm control).

Study burden and risks

AF ablation is a well-established and safe technique, known for its efficiency and minimal patient burden. Follow-up assessments will be conducted remotely using mHealth applications, reducing the need for frequent site visits and minimizing patient effort. Additional study procedures, such as blood sampling, extended electrocardiography, transthoracic echocardiography, and will be integrated into routine clinical care. Consequently, the number of additional procedures (blood sampling at randomisation and end of study for those participating in Cardiolines biobank substudy, extended ECG (5-minute duration) at randomisation and end of study, transthoracic echocardiogram at end of study, mHealth follow up and questionnaires and visits specifically for the study purposes is negligible, ensuring a streamlined and efficient study process.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- confirmed atrial cardiomyopathy (LAVI >34 ml/m2)
- ECG-confirmed atrial fibrillation
- age: 65-80 years old

Exclusion criteria

- permanent AF
- previous AF ablation
- heart failure NYHA III/IV
- severe aortic or mitral valve disease
- life expectancy < 1 year

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-07-2024
Enrollment:	604
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	08-05-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-11-2024
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	NCT06200311
CCMO	NL85861.042.23