Beat the Rhythm: the acute and long-term effects or prolonged walking exercise on the burden of atrial fibrillation in patients with atrial fibrillation

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

Summary

ID

NL-OMON57359

Source
ToetsingOnline

Brief title
Beat the Rhytm (BTR)

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, atrial flutter

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Interreg

Intervention

Keyword: atrial fibrillation, exercise, walking

Outcome measures

Primary outcome

The main study parameter is AF burden, as measured by time spent in AF.

Secondary outcome

Secondary study parameters are quality of life and blood biomarkers.

Study description

Background summary

Atrial fibrillation (AF) is the most common persistent cardiac arrhythmia. Exercise based cardiac rehabilitation has increasingly shown its potential benefits for AF. Walking as exercise intervention for AF patients has not been studied much, while being low cost and accessible and providing low-to-moderate intensity endurance exercise.

Study objective

The primary objective of this explorative study is to investigate the effect of 3-month preparation period of regular walking exercise prior to the Nijmegen 4-Day marches on objectively measured AF burden (primary parameter), self-reported AF burden and various blood biomarkers in AF patients and controls. The secondary objective is to investigate the effect of 4 consecutive bouts of prolonged walking exercise (i.e., 4-day Marches) on objectively measured AF burden (primary parameter), quality of life and various blood biomarkers in paroxysmal, permanent, and post-ablation AF patients and controls.

Study design

Longitudinal observational study.

Study burden and risks

For Objective 1, participants will visit the research centre twice in preparation of the 4-day Marches. Three months prior to (i.e., baseline) and 12-36 hours prior to (i.e., post-training) the 4-day Marches, participants report to our laboratory and we will collect data on personal characteristics, ECG measurements, blood pressure, body composition, blood samples, walking capacity, and questionnaires. In addition, during 3 assessments prior to the 4-Day Marches, participants will wear an ePatch (2-lead ECG measurements) to objectively measure AF burden and the ActivPAL to objectively evaluate physical activity levels for 7 consecutive days. Participants will fill in a training / daily physical activity diary throughout the preparation period prior to the 4-day Marches (May-Jul). For Objective 2, participants will wear an ePatch (2-lead ECG measurements) to continuously and objectively measure AF burden during the 4-Day Marches and its recovery (up to 72 hrs following completion). In addition, after each walking day, participants report to our laboratory to evaluate blood pressure, weight, blood samples, urine analysis and questionnaires. PPG measurements will be performed by the participant during 3 different timepoints, on 7 consecutive days, 3 times per day.
Only withdrawal of venous blood proposes a limited risk for the participants, since this is associated with a 5% risk of developing a haemorrhage. However, this will disappear within 2 weeks and is not associated with any (functional) limitations. We have graded the risk profile of this study as *negligible risk*.

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

- Age >18 years
- Able to understand and perform the study procedures
- Diagnosis of paroxysmal atrial fibrillation
- If the patient underwent an ablation procedure, the patient is eligible to participate if the atrial fibrillation has returned post-ablation

Exclusion criteria

- Age < 18 years
- No diagnosis of AF
- Diagnosis of permanent or persistent AF
- Patients with prior cerebro-/cardiovascular event (e.g., myocardial infarction) during the last 6 months
- Existence of a different disease impairing quality of life stronger than the underlying heart disease
- AF following intoxication, medication or acute infection
- Disability to understand the study protocol
- Planned holidays during the measurement weeks or during the ePatch wear weeks.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2025
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-03-2025
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL88341.091.24