The effectivity of lifestyle interventions and prevention in patients with atrial fibrillation referred for ablation; a randomised-controlled trial

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

Summary

ID

NL-OMON50896

Source
ToetsingOnline

Brief title
Prevention to improve Outcomes after PVI (POP-trial)

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, cardiac arrhytmia

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: ZonMW project TopZorg

Intervention

Keyword: ablation, atrial fibrillation, lifestyle intervention, remodeling

Outcome measures

Primary outcome

The main study endpoint is the number of cardioversions and re-ablations from patient inclusion up to 12 months after the ablation. We will also include events that occur before the ablation and within the first three months after the ablation, the so called blanking period. We expect that the proposed intervention will lead to a 30% reduction of the primary endpoint.

The primary outcome is the composite of hospital admissions for cardioversion and re-ablations with a follow-up of 12 months after the index ablation.

Secondary outcome

- Total hospitalisations for cardioversion
- Total hospitalisations for re-ablation
- The composite of mortality, stroke or hospitalisation for heart failure or acute ischemic events
- Total mortality
- Stroke
- Hospitalisation for heart failure or acute ischemic events
- Success of ablation
- Cancelation of index ablation
- Medical costs, resource utilization, and cost-effectiveness and patient value
- Quality of life

- Treatment burden

- Ablation procedure

- Adherence to lifestyle interventions

- Effect of OSA screening

- Exploration of patient experience and its main determinants in the new

outpatient clinic

- Exploration of staff experience and its main determinants in the new

outpatient clinic

Study description

Background summary

Atrial fibrillation (AF) is the most common cardiac arrhythmia affecting around 2% of the world population and its prevalence is expected to rise due to an aging population. This rise is accompanied with increasing rates of stroke, hospitalisation for heart failure and death. The burden of AF is mainly determined by hospitalisations, heart failure and thrombo-embolic events. Treatment of symptomatic AF consists of antiarrhythmic medication and catheter ablation. AF recurrence rate after 1 year is up to 60% with catheter ablation, with most recurrences in the first 6 months. Poor long-term outcomes may be due to inability to attenuate the progressive substrate for AF. Several modifiable risk factors have been linked as promoters for AF. Among those risk factors are obesity, hypertension, obstructive sleep apnea (OSA) and smoking. Treatment of these risk factors results in better AF outcomes. For example, long-term weight loss is associated with a 6-fold greater freedom from AF during 5 year follow-up. Bariatric surgery prior to AF ablation resulted into more freedom from AF. The RACE3-trial showed that AF patients with heart failure were more likely to remain in sinus rhythm if they were treated for their heart failure and hypertension. The ARREST-AF study also evaluated the effect of multiple risk factor management on ablation outcomes and showed improved AF burden and improvement of symptoms. The study might have been biased because of its observational design.
A nurse-led AF clinic has previously shown improvement in guideline adherence and patient education. Integrated care consists of community support and a multidisciplinary team, including an AF specialist nurse, a dietician, a sleep physician and an electrophysiologist. Integrated care approach is associated

with a reduction in all-cause mortality and cardiovascular hospitalisation in a population with atrial fibrillation. Furthermore, integrated care leads to lower health care costs, because future health consumption is lower.
Less is known about impact on patient value and quality of life (QoL). The CAPCOST trial showed that AF recurrences of more than 30 seconds up to 2 hours a month do not affect quality of life outcomes. Measuring total freedom from AF is not a good predictor for QoL in AF patients. At this point, there is not sufficient knowledge available about whether patients benefit from a specialized care outpatient clinic to treat the modifiable risk factors, including screening for OSA and lifestyle. We will be the first to test the effectiveness of a nurse-led outpatient clinic applying innovative technologies for personalized risk factor management and life style optimization in a prospective randomized controlled trial.
To our knowledge, this is the first large-scale study of its kind with patients that are referred for AF ablation. We hypothesize that an improved individualized and technology-supported care can improve patient value in atrial fibrillation.

Study objective

This study aims to validate an integrated care model that is standardized and can easily be carried out in any other hospital.

Primary objective
The primary objective is to determine the effect of a nurse-led, technology-supported, personalized care pathway on hospital admissions for cardioversion and re-ablation when compared with usual clinical care in patients with AF that are referred for ablation.

Secondary Objectives:
There are multiple secondary objectives.
- To determine cost-effectiveness and patient value as defined by Porter
- To evaluate ablation success rate in terms of the use of antiarrhythmics after three months
- To determine the effect on cancelation or deferral of the index ablation
- To determine general Quality of Life, using the EuroQol-5D questionnaire and to determine AF-related Quality of Life using the AFEQT questionnaire
- To determine the burden of Treatment using the Treatment Burden Questionnaire
- To evaluate the effect of treatment on the respective modifiable risk factors, using vital functions, weight and lab results.
- To test the role of OSA detecting technology (WatchPAT) in the AF population that is referred for atrial ablation, compared to other screening tools
- To evaluate patient experience and its main determinants in the new outpatient clinic
- To evaluate staff experience and its main determinants in the new outpatient clinic

Study design

This is a prospective, randomized, open label controlled trial. The study is performed in the Catharina hospital Eindhoven, a tertiary care hospital with regards to electrophysiology and ablation procedures. Patients with paroxysmal or persistent symptomatic atrial fibrillation that are referred for their first catheter ablation (also called the index ablation) are included in the prospective trial. Patients are randomized to standard clinical care or a highly specialized outpatient clinic for atrial fibrillation. This includes OSA screening with a specialized device (WatchPAT), screening and treatment of other modifiable risk factors and detailed questionnaires. The WatchPAT device has been validated for screening and detecting OSA in patients with AF (14). A nurse practitioner will also focus on lifestyle aspects with self-reporting technologies. Patients assigned to the usual-care group will have the ablation at standard time, without experiencing further delay. Patients assigned to the extensive care group will first receive treatment for their relevant risk factors and then undergo the ablation. The ablation will not be delayed for more than 6 months. We aim at treating the risk factors as soon as possible. If there are too many risk factors to be treated in a for the patient reasonable way, the physician will decide which risk factors will be treated. After the index ablation there is a follow-up time of 12 months. If patients have successful treatment at the outpatient clinic, this may lead to improvement of their AF symptoms and the possibility to cancel the planned ablation will be discussed with their treating cardiologist. Patients will still have a follow-up of 12 months after finishing treatment at the outpatient clinic.
We aim for a clear methodology so this study can be replicated and results can easily be applied in daily practice.

Intervention

The investigational treatment consists of multiple outpatient clinic visits which are conducted by a specialized nurse practitioner. The modifiable risk factors will be assessed during the intake visit, and relevant interventions are planned. In order to assess all of the risk factors, the patients are subjected to blood sampling, the measuring of vital functions and the WatchPAT, a home sleep apnea testing device, which is worn for one night. Lifestyle changes and medications will respectively be prescribed for weight management, blood pressure control, lipid management and glycaemic control. If applicable, patients will receive treatment for their OSA. The specific risk factor treatment plans are specified more clearly below in this section.
Patients are offered education and training concerning atrial fibrillation by face-to-face counselling. In order to achieve relevant behaviour changes related to the AF risk factors, behavioural determinants such as knowledge, self-efficacy and attitude will be addressed. Behavioural models such as the Integrated Behavioral Model (IBM) are used to understand the relevant

determinants and intervention mapping will be used to systematically develop an evidence-based intervention to initiate and maintain changes in alcohol consumption, smoking, dietary and physical activity behaviour.
Patients are instructed to use the VitalHealth Engage platform. This is a care platform for communication and care coordination. The patient can use the platform at home to report AF complaints, send home measurements (e.g. blood pressure) and can complete questionnaires. Furthermore, the platform can be regarded as an extension to the outpatient clinic visits. It supports the nurse practitioner in patient education and lifestyle changes, by providing the patient personalized content.
The time patients will spend undergoing the investigational treatment depends on which of the risk factors will be treated. We aim at finishing all treatments within 6 months after inclusion. If the patient has completed all relevant therapies or if 6 months have passed, the patient will undergo the ablation. If there are too many risk factors to treat within 6 months in a for the patient reasonable way, one or multiple risk factors might be ignored at the physicians discretion. After patients have had their index ablation, they will not receive any active further treatment of their risk factors. Patients are encouraged to continue their lifestyle treatment with support of the general practitioner. Patients in the control group will not visit the nurse-led outpatient clinic. They will immediately be planned for ablation. They will use the Engage app to answer quality of life questionnaires. The treating cardiologist is allowed to do interventions in the comparator group as he would normally do.
The several risk factor treatment plans and targets are specified in this section.

Blood pressure control
Blood pressure is measured during the first outpatient clinic by the nurse practitioner. Target blood pressure is systolic <140 mmHg and diastolic <90 mmHg. For patients with diabetes mellitus we target a blood pressure of 130/90 mmHg. Treatment is according the 2018 ESC Guidelines for the management of arterial hypertension. All hypertensive patients were advised a dietary salt restriction (<100 mmol/day; <5 gram/day).
Blood pressure monitoring at home is considered for follow-up and evaluating therapy success. During the last outpatient clinic visit before ablation a final blood pressure measurement will take place.

Lipid management
At the intake blood lipid analysis is done. The sample can be taken in a non-fasting state, since non-fasting samples have the same prognostic value as fasting samples. Patients are treated conform ESC 2019 guidelines on dyslipidaemias management. This may involve lifestyle changes and consultation of a dietitian. Eventually, this also leads to treatment with an HMG-CoA reductase inhibitor or a cholesterol absorption inhibitor. Fibrates are used for isolated hypertriglyceridemia. Evaluation of therapy takes place at 3 months with a new blood lipid analysis.

Glycaemic control
In patients with known diabetes, target HbA1c was <53 mmol/mol. Better treatment of hyperglycaemia was advised to the physician responsible for the treatment of diabetes, for example, the general practitioner or the endocrinologist. This may also include the consultation of a dietitian.
Diabetes mellitus de novo was suspected in patients with HbA1c >48 mmol/mol and fasting plasma glucose >7.0 mmol/L. They will be referred to their general practitioner for further treatment. During the last outpatient clinic visit before ablation new HbA1c check will take place/

Alcohol
Alcohol reduction is promoted on the outpatient clinic. Men who drink alcohol should be advised to limit their consumption to 14 units per week and women to 8 units per week (1 unit is equal to 125 mL of wine or 250 mL of beer). Alcohol-free days during the week and avoidance of binge drinking are also advised. More strict alcohol reduction is promoted in patients that also follow the hypertension and weight management program.

Smoking
Smokers were offered support with smoking cessation. They were offered a training by a certified nurse and a smoking cessation programme that lasts approximately 6 weeks.

Obstructive Sleep Apnea
Obstructive sleep apnea is diagnosed with the WatchPAT device. The WatchPAT device has recently been approved for screening and detecting OSA in patients with AF. All patients in the specialized outpatient clinic will wear the WatchPAT for one night. This results in the probable diagnosis and severity of obstructive sleep apnea. A sleep physican will be consulted for further testing and treatment of OSA. Therapy is offered when AHI was >5/hour.

Weight management
Patients were defined as overweight when they had a body mass index (BMI) above 27 kg/m2. Weight reduction was promoted by offering support counselling and a meal plan with a dietician. This consists of a low-calorie meals with a low glycaemic index. Support focused on behaviour modification. At first, we target a >10% weight reduction. If patients were still overweight after reaching this goal, further weight loss is promoted. We aim at having a healthy diet low in saturated fat with focus on wholegrain products, vegetables, fruit and fish. Lifestyle advice constituted dietary salt restriction 5 gram/day.

Physical (in)activity
Patient are offered to participate in a physical activity programme. Overweight patients will be recommended to improve physical activity, with a target of 3.5-7 hours of merely vigorous physical activity per week or 30-60 min most days. Regular aerobic exercise (e.g. at least 30 min of moderate dynamic exercise on 5-7 days per week) is recommended. Patients that endure complaints

during exercise are also offered support with physical activity at a specialized cardiac rehabilitation centre. This includes training under supervision of a physiotherapist twice a week during an hour.

Study burden and risks

To some extent there might be a burden for patients in both the interventional and control group.
Patients from the interventional group will have to visit the hospital at least 4 times in 18 months of participation. The first visit will last 45 minutes; follow-up visits will last 10 minutes. Patients will have a physical examination, the will have an ECG and they will have blood sampling. At 4 different moments the patients will have to fill out questionnaires. Patients will undergo a sleep examination at home during one night. This involves wearing a sensor at night. The burden for patients is estimated to be at least 17 hours. More hospital visits and consultations with a dietician, physiotherapist or somnologist will come on top of this, depending on relevant risk factors.
Patients from the control group will have a burden of 3 hours. They will undergo blood sampling three times in 18 months. The will also have to answer questionnaires in the Engage app three times in 18 months.
The risk for participants in the interventional group is that their ablation will be delayed for a maximum of 6 months, depending on their risk treatment strategy.
Participants in de control group will not experience any delay of intervention.

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

Patients with paroxysmal or persistent atrial fibrillation referred for initial catheter ablation
Age 18-75 years
The patient should have at least on treatable risk factor (BMI >=27 kg/m2, hyperlipidaemia, hypertension, diabetes mellitus with HbA1c >=53 mmol/mol, active smoking, or excess alcohol use)
Patients are willing and able to use the VitalHealth Engage platform on their own preferred device

Exclusion criteria

Longstanding persistent atrial fibrillation (persistent atrial fibrillation for more than 1 year)
Permanent atrial fibrillation
Asymptomatic atrial fibrillation
Prior ablation
Severe valvular heart disease
Prior or soon foreseen implantation of cardiac device
Acute coronary syndroom < 3 months before inclusion
Unstable heart failure NYHA IV or heart failure necessitating admission <3 months before inclusion
Cardia surgery <3 months before inclusion
Life expectancy <1 year
Pregnancy

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-12-2021
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	a. WatchPAT; b. VitalHealth Engage
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-08-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-02-2024
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL77792.100.21