Accelerated Pacing for Improved Quality of Life in Symptomatic Atrial Fibrillation Patients undergoing Pace-and-Abate Strategy with Left Bundle Branch Area Pacing: a Randomized Controlled Pilot Trial: PACE-AF

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

Summary

ID

NL-OMON57043

Source
ToetsingOnline

Brief title
PACE-AF

Condition

- Cardiac arrhythmias

Synonym
Atrialfibrillation, Supraventricular tachycardia

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Accelerated Pacing, Atrial Fibrillation, Pace-and-ablate, Quality of Life

Outcome measures

Primary outcome

Difference in HRQoL between a lower rate of 80 bpm and a lower rate of 60 bpm,

based on the Minnesota Living with Heart Failure Questionnaire (MLHFQ),

determined at 6 months follow-up.

Secondary outcome

- The acute hemodynamic effects of (accelerated) pacing at time of AVNA:

o Pulmonary Capillary Wedge Pressure (PCWP)

o Cardiac Output (CO)

o Systemic arterial blood pressure

- The long-term effect of accelerated pacing on:

o HRQoL, based on the MLHFQ and SF-36 questionnaires.

o NT-proBNP levels

o Device detected AF burden

o Device detected daily activity comparing accelerated- vs control rate

o Echocardiographic measurements (LVEF, LVEDD, LVESD, LAVI, LA strain)

- Symptoms experienced as a result of (accelerated) pacing based on the AFEQT

questionnaire

Study description

Background summary

Permanent pacemaker implantation combined with atrioventricular node ablation (AVNA) reduces symptoms and improves health-related quality of life (HRQoL) in patients with symptomatic atrial fibrillation (AF). A high percentage of conventional right ventricular pacing increases the risk for pacing-induced cardiomyopathy, a risk which is presumably minimised by a form of conduction sys-tem pacing, termed left bundle branch area pacing (LBBAP). LBBAP attempts to recreate the normal physiologic activation of the heart through stimulation of the heart*s own natural conduction sys-tem, thereby maintaining ventricular synchrony. This strategy may be particularly important in pa-tients with heart failure with preserved ejection fraction (HFpEF), a diagnosis that frequency coex-ists with AF. The long-term programming of a patient undergoing a *pace-and-ablate strategy* (pacemaker implantation and AVNA), is such that the lower rate of the pacemaker is routinely set to 60 bpm. Previous studies have shown that accelerated pacing (ie. programming the pacemaker to a lower rate of 80bpm) may improve HRQoL in a subset of patients with HFpEF. It is therefore hypothesized that accelerated pacing will improve HRQoL in patients with symptomatic AF under-going a pace and ablate strategy, when compared to pacing at 60 bpm, which is standard of care.

Study objective

To determine the effect of accelerated pacing (lower programmed rate of 80 bpm) compared to pacing at the standard programmed rate of 60 bpm on HRQoL in symptomatic AF patients undergo-ing pace-and-ablate strategy with LBBAP.

Secondary objectives:
- To study, in a subset of participants who give informed consent, the acute hemodynamic effect of accelerated pacing rates on pulmonary capillary wedge pressure (PCWP), cardiac output and arterial blood pressure, among AF patients undergoing a pace-and-ablate strategy with LBBAP.
- To study the long-term (6 months) effects of accelerated pacing among AF patients undergoing a pace-and-ablate strategy with LBBAP by measuring NT-proBNP levels, device detected AF-burden and daily activity, by evaluating HRQoL questionnaires (SF-36), and by assessing echocardiographic measurements (LVEF, left ventricular ejection fraction; LVEDD, left ventricular end-diastolic diameter; LVESD, left ventricular end-systolic diameter; LAVI

left atrial volume index; diastolic parameters; strain) compared to pacing at the standard of care lower rate of 60bpm.
- To investigate whether participants experience symptoms of accelerated pacing (such as palpitations), based on the Atrial Fibrillation Effect on Quality-of-life (AFEQT) questionnaire, compared to standard of care.

Study design

Randomized, single center, prospective, single blinded, parallel group, pilot-trial.

Intervention

- 1:1 randomization to a lower rate of DDDR 80 bpm (intervention) or a lower rate of DDDR 60 bpm (control). Duration of the study is 6 months.

In a subset of participants:
- Right heart catheterisation and invasive blood pressure measurements will be conducted to evaluate acute hemodynamic effects of different (accelerated) ventricular pacing rates during the standard of care AV node ablation.

Study burden and risks

The additional burden for participating in the study comprises of completing questionnaires at three occasions. There are no additional risks with regards to the pacemaker implantation and AV-NA procedure, as these are standard of care and not part of the study. Pacing with moderately elevated lower rates has not been associated with an increased risk for heart failure in HFpEF patients.

The (optional, in patients who give additional informed consent) right heart catheterisation is part of the study and will be performed during the same session as AVNA, for which an additional femoral vein puncture is required. The most reported serious complication is pulmonary artery damage, which occurs in < 0.5%. In addition, there is a low risk of pacemaker lead dislodgement during right heart catheterisation. Local vascular complications of the venous puncture like bleed-ing, infection or damage to the vessel wall may occur but are rare.

Additional invasive arterial blood pressure measurements are performed by placing a sheath in the femoral artery which is not routine care during AVNA. Local vascular complications of the arterial puncture like bleeding, infection or damage to the vessel wall may occur but are rare.

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

Adults >18 years of age
Referred for pace-and-ablate strategy with left bundle branch area pacing for symptomatic AF
Left ventricular ejection fraction >40%
Willingness to participate, to understand the intructions and fill out the questionnaires

Exclusion criteria

Infiltrative or constrictive cardiomyopathy
Severe valvular heart disease

Participation in another interventional clinical trial
recent myocardial infacrtion, Transient Ischemic Attack, Cerebro-vascular accident

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-01-2025
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Pacemaker
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-10-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL86643.068.24