Pacing Away From Heart Failure: Left bundle branch area pacing or biventricular pacing in patients with atrial fibrillation and left ventricular dysfunction

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Primary objectives:1. To compare LVESV change between LBBAP and biventricular pacing in patients with AF and LV dysfunction.Secondary objectives: 2. To compare change in quality of life, New York Heart Association functional class, 6-minute walking...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON56990

Source
ToetsingOnline

Brief title
Pacing Away From Heart Failure

Condition

- Heart failures

Synonym
cardiac pump failure, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac resynchronization therapy, Conduction system pacing, Heart failure, Pacing

Outcome measures

Primary outcome

Left ventricular end-systolic volume change compared to baseline.

Secondary outcome

NYHA functional class, Minnesota Living with Heart Failure Questionnaire

(MLHFQ), 6-minute walking distance, ECG (vectorcardiographic QRS area, QRS

duration), echocardiography (LVESV, LVEF, global longitudinal strain),

NT-proBNP, lead and device performance (sensing, pacing, expected battery

life), complications and costs will be evaluated for each pacing mode.

Study description

Background summary

Patients with AF and LV dysfunction may require ventricular pacing because of bradycardia, AV junction ablation, or for cardiac resynchronization therapy (CRT). RV pacing is associated with the risk of adverse LV remodelling and heart failure, in particular in those with pre-existing LV dysfunction. Both LBBAP and biventricular pacing can prevent LV dyssynchrony. It is unknown which pacing mode best prevents or reverses LV adverse remodelling in patients with AF who require ventricular pacing or CRT.

Study objective

Primary objectives:
1. To compare LVESV change between LBBAP and biventricular pacing in patients

with AF and LV dysfunction.
Secondary objectives:
2. To compare change in quality of life, New York Heart Association functional class, 6-minute walking distance, QRS duration, vectorcardiographic QRS area, LVEF, global longitudinal strain and NT-proBNP between LBBAP and biventricular pacing in patients with AF and LV dysfunction.

Study design

Randomized patient and assessor blinded non-inferiority cross-over trial.

Intervention

Patients will be randomized according to a crossover design to 6 months of LBBAP followed by 6 months of biventricular pacing, or vice cersa. Patients will be followed according to routine clinical practice.

Study burden and risks

For the purpose of this randomized controlled trial, patients will also receive a LBBAP lead. The additional risk of serious adverse events is ~1.5% (lead dislodgement 1.1%, 0.4% acute coronary syndrome [all managed conservatively without further sequelae in prior studies]).(1)
Patients who participate in the trial will also be asked to perform 3 six-minute walking tests and to fill out 3 questionnaires. All other procedures are performed according to routine clinical practice.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Adults >=18 years with permanent AF and LVEF < 50% who either require ventricular pacing because of bradycardia including patients undergoing AV junction ablation, or have an indication for cardiac resynchronization therapy.
- Expected percentage of ventricular pacing > 40%
- >= 3 months of heart failure medication optimization

Of note, patients who already have a device, but require an upgrade to a cardiac resynchronization therapy device, can also be included

Exclusion criteria

- Age < 18 years
- Pregnancy or active pregnancy wish
- Not eligible for implantation of an RV lead, LBBAP lead, or LV lead in the coronary sinus
- The need for a right-sided device implantation
- Recent valve intervention/surgery or acute myocardial infarction (< 6 months)
- NYHA functional class IV heart failure, left ventricular assist device or cardiac transplant

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-12-2024
Enrollment:	17
Type:	Actual

Medical products/devices used

Generic name:	Pacemaker lead 3830 SelectSecure
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-08-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-02-2025
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL84372.058.23