Pulmonary vein isolation or atrioventricular node ablation in patients with heart failure and symptomatic atrial fibrillation diminishing CRT response (PULVERISE-AF-CRT): A randomized study

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Primary objective: to study in patients with heart failure and AF whether PVI or atrioventricular node ablation is non inferior with regard to all-cause mortality, cardiovascular hospitalization or changes in quality of life. Secondary objective: to...

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

Summary

ID

NL-OMON52003

Source
ToetsingOnline

Brief title
PVI vs AVN ablation: PULVERISE-AF-CRT

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation, heartfailure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ablation, Atrial fibrillation, CRT, Heart failure

Outcome measures

Primary outcome

The primary end point is defined as the hierarchical occurrence of all-cause death, cardiovascular hospitalization (heart failure or stroke), and the change in quality of life at 1 year.

Secondary outcome

Death from any cause, unplanned hospitalization related to heart failure, death from cardiovascular disease, cerebrovascular accident, unplanned hospitalization for cardiovascular disease, and any hospitalization. Furthermore changes in the Kansas city cardiomyopathy questionnaire were assessed. Also procedure related adverse events and atrial fibrillation-free intervals were assessed.

Study description

Background summary

Pulmonary vein isolation (PVI) is currently the cornerstone non pharmacological therapy for drug-refractory atrial fibrillation (AF). Where rhythm control has been shown to be inferior as compared to rate control in older trials. New data suggest that for patients with heart failure and AF PVI may improve prognosis (mortality) as compared to medical rate or rhythm control. Whether optimal rate control as can be achieved with atrioventricular node ablation is comparable with regard to all-cause mortality of heart failure hospitalization to PVI in

patients with heart failure and AF is unknown.

Study objective

Primary objective: to study in patients with heart failure and AF whether PVI or atrioventricular node ablation is non inferior with regard to all-cause mortality, cardiovascular hospitalization or changes in quality of life.
Secondary objective: to study cardiovascular morbidity related to PVI or atrioventricular node ablation.

Study design

Study design: Single centre, randomized study.

Intervention

all patients will undergo either PVI or atrioventricular node ablation.

Study burden and risks

Most investigations during the study are standard clinical care. PVI is shown to be effective to increase left ventricular ejection fraction in patients with heart failure. Also AV node ablation might be beneficial and is recommended by current guidelines to achieve adequate rate control. However, there have been no trials to randomize patient to either of these treatment strategies with relation to major cardiovascular outcomes

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

• Presence of a cardiac resynchronization therapy device (CRT-D or CRT-P) and optimal medical therapy according to current guidelines.
• Patients with paroxysmal or persistent AF, having AF or HF related symptoms.
• Patient with paroxysmal AF should have >25% burden or inadequate biventricular pacing (<95%) based on device counters.
• The patient is willing and able to comply with the protocol and has provided written informed consent.
• Age >= 18 years

Exclusion criteria

• Documented left atrial diameter > 6 cm (parasternal long axis).
• Longstanding persistent AF longer than 2 years.
• Contraindication to chronic anticoagulation therapy or heparin
• Previous left heart ablation procedure for AF
• Acute coronary syndrome, cardiac surgery, angioplasty or stroke within 2 months prior to enrolment
• Untreated hypothyroidism or hyperthyroidism
• Enrolment in another investigational drug or device study.
• Woman currently pregnant or breastfeeding or not using reliable contraceptive measures during fertility age.
• Mental or physical inability to participate in the study.
• Listed for heart transplant.
• Cardiac assist device implanted.
• Planned cardiovascular intervention.
• Life expectancy <= 12 months.
• Uncontrolled hypertension.

• Requirement for dialysis due to terminal renal failure.
• Participation in another telemonitoring concept

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2021
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Ablatie katheters
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-05-2022
Application type:	First submission
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
CCMO	NL76855.042.21