Surgical Septal Myectomy versus Percutaneous Transluminal Alcohol Septal Ablation in Patients with Hypertrophic Obstructive Cardiomyopathy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56423

Source
ToetsingOnline

Brief title
AMARONE

Condition

- Myocardial disorders

Synonym
HOCM; thickened heart muscle

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Ziekenhuis

Intervention

Keyword: HOCM, LVOT obstruction, MORROW, PTSMA

Outcome measures

Primary outcome

The primary study question is whether ASA is non-inferior to SSM in the improvement of exercise capacity.

The primary endpoint is the exercise capacity in the form of Metabolic Equivalent (METs) which will be assessed with a bicycle ergometry exercise test (difference in exercise capacity in Metabolic Equivalents) performed before and 1 year after invasive treatment.

Secondary outcome

Secondary endpoints are all-cause mortality, cardiovascular mortality (defined as death resulting from acute myocardial infarctions, sudden cardiac death, death due to heart failure, death due to stroke, death due to cardiovascular procedures, death due to cardiovascular hemorrhage and death due to other cardiovascular causes) and Transient Ischemic Attack. Also readmittance, occurrence of atrial fibrillation, ventricular arrhythmias (aborted ventricular fibrillation, ventricular tachycardia), complete heart block requiring permanent pacemaker implantation, and major bleeding, re-intervention, blood sample analysis (ex. NT-pro-BNP, Troponine and creatine-kinase (CK)), symptoms and quality of life evaluation using SF-36 questionnaire will be captured.

Follow-up will be on 1, 3 and 5 years.

Study description

Background summary

Hypertrophic cardiomyopathy (HCM) is the most common inheritable cardiac disease. Obstruction of the left ventricular outflow tract (LVOT) at rest or during exercise is present in the majority of patients and is referred to as hypertrophic obstructive cardiomyopathy (HOCM). LVOT obstruction is associated with heart failure symptoms, exertional syncope, and sudden cardiac death. Conventional pharmacologic treatment might improve functional limitation but has no effect on mortality. Two-dimensional (2D) echocardiography is regarded as the initial step in evaluation of hypertrophy. However cardiac magnetic resonance imaging (MRI) enables more precisely localization and degree of left ventricular hypertrophy and in addition is able to quantify the extent and distribution of myocardial fibrosis, which appears to have an impact on outcomes. MRI is thus superior to 2D echocardiography and is therefore recommended in the European and American guidelines. For more than 50 years surgical septal myectomy (SSM) has been an excellent treatment to relieve LVOT obstruction in patients with HOCM, however, for more than 2 decades already, alcohol septal ablation (ASA) is a good alternative. Therefore, both the European and American Guidelines recommend to consider both treatment options in patients with severe limiting symptoms refractory to maximum medical management and marked outflow obstruction (peak instantaneous gradient >= 50mmHg at rest or with physiologic provocation). Observational studies suggest that both mortality and sudden cardiac death (SCD) risk are similarly lowered in patients after ASA and SSM. Permanent pacemaker dependency and need for additional septal reduction therapy is higher in patients who undergo ASA compared to SSM. In contrast, SSM compared to ASA has a much longer recovery time as well as more thoracotomy related complications.

Study objective

The aim of this registry is to compare functional status among patients with highly symptomatic obstructive HCM despite optimal medical treatment who undergo Alcohol Septal Ablation to Surgical Septal Myectomy. This study will therefore, compare the outcomes of functional status of both treatments for symptomatic patients with HOCM.

Study design

A prospective, multicenter, registry study which two study arms, alcohol septal

ablation and surgical septal myectomy.

Intervention

Patients will be treated with transcatheter ASA or SSM according to hospitals` local standards.

Study burden and risks

ASA, SSM and related products during the intervention, bicycle ergometry exercise test, blood sampling, echocardiography and CMR are part of daily clinical practice and there are no additional burden or risks.

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

1. Age between 30-80 years
2. HOCM eligible for either SSM or ASA by a heart team (multi-disciplinary team)
3. LVOT obstruction >=50 mmHg at rest or during physiological provocation by TTE
4. Symptomatic (NYHA class >=2) and/or syncope due to HOCM

Exclusion criteria

1. Unable to give informed consent
2. A life expectancy of less than 1 year
3. Concomitant intrinsic valvular disease requiring surgery in accordance with current guidelines
4. Concomitant coronary artery disease not amendable to PCI and thus requiring coronary artery bypass surgery
5. Not able to perform bicycle ergometry exercise test

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2021
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	13-07-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-02-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-12-2023
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	NL73176.100.20