Prevalence of patent foramen ovale (PFO) in patients with angina and documented coronary artery vasospasm

Published: 19-08-2021
Last updated: 15-05-2024

The main objective of this study is to assess the prevalence of PFO and RLS in patients with angina and documented coronary artery vasospasm.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON51029

Source
ToetsingOnline

Brief title
PROVA-study

Condition

- Coronary artery disorders
- Cardiac and vascular disorders congenital

Synonym
Patent Foramen Ovale

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AUMC

Intervention

Keyword: Angina, Coronary artery vasospasm, Patent Foramen Ovale, Prevalence

Outcome measures

Primary outcome

- Prevalence of PFO and RLS in patients with documented coronary artery vasospasm (TTE with agitated-saline)

- Quality of Life at baseline --> Seattle Angina Questionnaires (SAQ) score and Migraine Disability Assessment Questionnaire (MIDAS) score

Secondary outcome

- Exercise testing in patients with coronary artery vasospasm and RLS

- QoL during follow up

- Number of episodes of angina symptoms will be assessed

- Number of episodes of migraine headaches will be assessed

- Association between exercise capacity, QoL and exercise-related oxygen (de)saturation in patients with coronary artery vasospasm and a RLS

- Measurement of VO2 max during exercise testing

- Measurement of oxygen saturation

Study description

Background summary

Patent Foramen Ovale (PFO) and atrial septal defect (ASD) have been associated with the occurrence of paradoxical embolism. Current guidelines and position reports recommend diagnostic work-up in young patients with cryptogenic stroke and closure of PFO in selected cases. In addition to the association between PFO and cryptogenic stroke, there are many reports of patients with a PFO that suffer a systemic arterial embolism causing arterial occlusion of extremities,

renal infarcts and acute myocardial infarction with paradoxical embolism in the coronary artery.
In addition, PFO has been associated with migraine with aura, suggesting that vaso-active components of the venous circulation, when bypassing the lungs through a right-to-left-shunt (RLS), may modulate the cerebral microcirculation causing migraine. Although recent randomized trials have not demonstrated that PFO closure is superior to medical therapy in migrainers, PFO closure has been shown to abolish migraine in 9% of patients and reduce the number of monthly migraine days with 3 days in a recent meta-analysis.
In a recent study, an association was demonstrated between migraine and coronary spasm, although there was no association with coronary heart disease (CHD) events. Importantly, anti-migraine medication such as triptans may cause coronary spasm. RLS can be a trigger for the occurrence of migraine headaches and is postulated to be a trigger for episodes of angina complaints due to coronary spasm.

Study objective

The main objective of this study is to assess the prevalence of PFO and RLS in patients with angina and documented coronary artery vasospasm.

Study design

This is a single-center, prospective, cohort study. Open label with follow up at 6 months.

Study burden and risks

After signing informed consent, patients will undergo transthoracic echocardiography (TTE) with intravenous agitated-saline to evaluate the presence of RLS. Patients with a PFO and RLS will be invited to undergo exercise testing including VO2max and oxygen saturation measurement. Patients will be surveyed with the Seattle Angina Questionnaires (SAQ) and Migraine Disability Assessment Questionnaire (MIDAS). They will report general well-being, daily activities, and episodes of angina and migraine. Patients with RLS will be asked to measure oxygen saturation with a pulsoximeter at set intervals during the follow-up period, e.g. before and during exercises.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9

Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Adult patients with documented coronary artery vasospasm with an intracoronary acetylcholine provocation testing
- Able to measure oxygen saturation with a pulsoximeter
- Able to undergo TTE with agitated saline testing
- Able to perform Valsalva manoeuvre for reliable RLS assessment
- Able to undergo VO2max exercise testing

Exclusion criteria

- Life expectancy < 1 year
- Active infection requiring antibiotic therapy, including endocarditis or other disabling serious illness
- Absence of images of adequate quality with TTE due to anatomical reasons (*no adequate TTE windows**)
- Inability to provide written informed consent
- Inability to comply with outpatient visit at hospital during 6 months follow-up

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-09-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.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

ID: 27068
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL78011.018.21
OMON	NL-OMON27068