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

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This study will investigate prevalence of PFO in patients with documented coronary artery vasospasm

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27068

Source
Nationaal Trial Register

Brief title
PROVA-study

Health condition

Patent foramen ovale (PFO); Coronary artery vasospasm

Sponsors and support

Primary sponsor: Investigator initiated study, Sponsor AUMC
Source(s) of monetary or material Support: Investigator initiated study, Sponsor AUMC

Intervention

Outcome measures

Primary outcome

- Prevalence of PFO and RLS in patients with documented coronary artery vasospasm - QoL, SAQ score and 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

Rationale: 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. 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 population: A total of 100 patients with angina and documented coronary artery vasospasm. In the participating site there is a specific interest and knowledge in patients with non-obstructed coronary arteries (ANOCA). Patients with angina whom undergo an intracoronary acetylcholine provocation testing are monitored by their treating physician.. The treating physician will inform the patients about the study during an outpatient clinical visit if they met the in- and exclusion criteria. Main study parameters/endpoints: All participating patients will undergo TTE with agitated-saline to assess RLS. Patients with a PFO and RLS will undergo exercise testing with VO2max and oxygen saturation measurement. Quality of Life (QoL) will be assessed at baseline, 6wks and 6 months using the Seattle Angina Questionnaires (SAQ) and Migraine Disability Assessment

Questionnaire (MIDAS) (see appendix I and II). Visit at 4-6 weeks after baseline assessment. Follow-up will be at 6 months. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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. The oxygen saturation will be measured with a pulsoximeter during follow up at the outpatient clinic.

Study objective

This study will investigate prevalence of PFO in patients with documented coronary artery vasospasm

Study design

6 months follow-up

Contacts

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Eligibility criteria

Inclusion criteria

- Adult patients with documented coronary artery vasospasm with an intracoronary acetylcholine provocation testing - Able to measure oxygen saturation with a pulsoximeter at the outpatient clinic - 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 non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	27-09-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-09-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51029
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9727
CCMO	NL78011.018.21
OMON	NL-OMON51029

Study results