# 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

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON27068

**Bron**
NTR

**Verkorte titel**
PROVA-study

**Aandoening**

Patent foramen ovale (PFO); Coronary artery vasospasm

### Ondersteuning

**Primaire sponsor:** Investigator initiated study, Sponsor AUMC
**Overige ondersteuning:** Investigator initiated study, Sponsor AUMC

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

- Prevalence of PFO and RLS in patients with documented coronary artery vasospasm

- QoL, SAQ score and MIDAS score

# Toelichting onderzoek

**Achtergrond van het onderzoek**

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.

**Doel van het onderzoek**

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

**Onderzoeksopzet**

6 months follow-up

# Contactpersonen

## Publiek

Amsterdam UMC, location AMC
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020-5666407

## Wetenschappelijk

Amsterdam UMC, location AMC
Abdelhak El Bouziani

020-5666407

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 27-09-2021 |
| Aantal proefpersonen: | 100 |
| Type: | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 13-09-2021 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51029
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten