The value of transthoracic contrast echocardiography after pulmonary arteriovenous malformation embolization

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Primary Objective: 1. To evaluate if chest CT can be withheld in post-embolization patients without or with a minimal pulmonary right-to-left shunt, based on:a. The evaluation of the grade of pulmonary RLS on TTCE after PAVM embolization in patients...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON51776

Source
ToetsingOnline

Brief title
Value of TTCE after PAVM embolization

Condition

- Cardiac and vascular disorders congenital
- Vascular disorders NEC

Synonym
Hereditary taemorrhagic telangiectasia (HHT), Rendu-Osler-Weber disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: deels eigen bijdrage maatschap;deels

financiering door St. Antonius Onderzoeksfonds

Intervention

Keyword: Embolization, Hereditary haemorrhagic telangiectasia, Pulmonary arteriovenous malformation, Transthoracic contrast echocardiography

Outcome measures

Primary outcome

Primary outcomes include:

- the pulmonary RLS grade on TTCE: will be determined by the maximum number of microbubbles in the left-sided heart chambers visualized in one frame: 1-30 microbubbles (grade 1), 30-100 microbubbles (grade 2), or >100 microbubbles (grade 3).

- the change in echo density on TTCE: will be determined using ImageJ (National Institutes of Health, Bethesda, MA, USA). Three images, two baseline measurements and one frame with the maximum number of microbubbles in the left ventricle, were selected and transported to ImageJ. The average of the two baseline measurements will be calculated, as well as the absolute change in echo density - with the LV baseline considered as darkest possible. A complete white image has a value of 255. The corrected change in echo density will be calculated by dividing the change in ED in the LV (maximum - baseline) by the maximum change possible (255 - baseline).

- Presence of macroscopic PAVMs (yes/ no, number), type of PAVMs, presence of reperfusion, recanalization or inadequate embolization, indication for additional treatment on chest CT.

Secondary outcome

Clinical outcome measures, including: symptoms (dyspnoea, haemoptysis, migraine), complications (cerebral infarction, cerebral abscess, transient ischemic attack), and oxygen saturation - for the description of the study population.

Study description

Background summary

A pulmonary arteriovenous malformation (PAVM) is a direct connection between the pulmonary artery and -vein, creating a right-to-left shunt. Most PAVMs are associated with hereditairy haemorrhagic telangiectasia, a rare genetic vascular disease characterized by recurrent epistaxis, mucocutaneous telangiectases, and visceral arteriovenous malformations. In PAVMs, by bypassing the capillary network, emboli (with or without bacteria) may gain access to the systemic circulation. Therefore, PAVMs are associated with an increased risk of neurologic complications (brain abscess, TIA, stroke). Treatment of PAVMs with embolization decreases the risk of these neurologic complications.
Currently, the follow-up after embolization is consisting of a chest CT after six months, followed by every 3-5 years. Altogether, leading to significant exposure to ionizing radiation. Also, chest CT only provides information about the anatomy. Previous research demonstrated a remaining RLS in 90% of the patients- however not taken the RLS grade into account. In a treatment-naïve population, a chest CT can be safely withheld in patients with only a minimal RLS. Also, a small study including 30 patients suggests that is it to withhold a chest CT in patients without or with a minimal RLS after embolotherapy. However, since this is only a small study, further research is necessary.
In our clinical practice, the follow-up after embolization consists of both TTCE and chest-CT in all patients: to provide both information about the size of the shunt (physiology, with TTCE) as well as the anatomy (chest-CT).

Study objective

Primary Objective:
1. To evaluate if chest CT can be withheld in post-embolization patients without or with a minimal pulmonary right-to-left shunt, based on:
a. The evaluation of the grade of pulmonary RLS on TTCE after PAVM embolization in patients with an indication for retreatment based on chest CT (for a re-treatable PAVM or new PAVM). (retrospective)
2. To evaluate if chest CT can be withheld in post-embolization patients with a

stable minimal or moderate right-to-left shunt, based on:
a. The evaluation of the pulmonary RLS grade on TTCE 6 months, 2-3 years and 5 years after embolization with the indication for re-treatment on chest CT. (retrospective) A stable RLS is defined as remaining the same RLS-grade category (absent, minimal (grade 1), moderate (grade 2)).

Secondary Objective(s):
3. To evaluate the correlation between change in echo density and the indication for retreatment (retrospective) to evaluate the additional value of the use of the change in ED in the number of needed chest-CTs.
4. To evaluate if TTCE directly after embolization can replace the follow-up 6 months after embolization by exploring the underlying biology of shunt recurrence/ persistence after embolization, by
a. The evaluation of the grade of pulmonary RLS on TTCE directly after and 6 months after embolization. (prospective)
b. The evaluation of the change in ED on TTCE directly after and 6 months after embolization. (prospective)

Study design

Retrospective part: in our current clinical practice, after the embolization, follow-up consists of TTCE and chest-CT after 6 months, 3 years and subsequently every 5 years. Data will be retrospectively collected from included patients.

Prospective substudy: TTCE will be performed directly after embolization during hospital admission.

Endpoints regarding the grade of the pulmonary RLS and change in ED will be collected by reviewing the TTCEs. The chest-CTs will be reviewed by an experienced interventional radiologists and evaluated for the presence of reperfusion, recanalization, inadequate embolization, indication for additional embolization. The chest CT before embolization and the images of the embolization procedure and angiography directly after embolization will be available as well, to optimize this evaluation. Endpoints regarding clinical outcome measures (the presence of symptoms and occurrence of cerebral complications) will be collected directly after embolization and at follow-up visits - for description of the study population.

Study burden and risks

Inclusion in the retrospective observational study does not affect the patient, not in a beneficial or negative way.
Participation in the prospective substudy includes an extra TTCE directly after embolization, requiring an intravenous line and time. Placement may be associated with some pain, and in some cases cause a hematoma. Also, in the

presence of large PAVMs - injection of the microbubbles may in rare cases cause migraine. No benefits are present for participating patients.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult patients who underwent embolization for pulmonary arteriovenous malformation and have a follow-up TTCE 6 months after embolization. (restrospective part)
Adult patients with a treatable pulmonary arteriovenous malformation who will undergo embolization at the St. Antonius Hospital. (prospective part)

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-04-2023
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	08-07-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	02-01-2025
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	NL80334.100.22