SIlent embolic cerebral infarction after radial access in interventional radiology procedures

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Ethical review	Approved WMO
Status	Pending
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON47948

Source
ToetsingOnline

Brief title
Silembolic

Condition

- Embolism and thrombosis

Synonym
Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acute silent stroke, Embolic Cerebral infarction, Intervention radiology, Radial acces

Outcome measures

Primary outcome

Quantify the prevalence of SECI after transradial interventional radiology

procedures using MRI.

Secondary outcome

Secondary Objective(s): Difference in SECI between right- or left-sided radial

access.

Study description

Background summary

Traditionally, endovascular access for interventional radiology procedures is obtained by trans-femoral access (TFA) providing access to virtually all vascular territories. Trans-radial access (TRA) and even distal radial access (DRA) are increasingly used as alternative access methods. Access through the radial artery has shown lower major complication rates, earlier mobilization and discharge, reduced costs and better patient satisfaction compared to TFA.

Acute stroke is a rare complication following radial access demonstrated in coronary interventions, but asymptomatic thromboembolic events, silent embolic cerebral infarctions (SECI), are more prevalent. Silent infarcts are associated with adverse cognitive and neurological consequences.
However, in abdominal interventional radiology procedures, the aortic arch is only passed once, without exchange of the catheters in contrast to percutaneous coronary interventions in which (guiding) catheters are frequently exchanged. Therefore, the likelihood of silent embolic cerebral infarctions in interventional radiology is theoretically lower. The main objective of this study is to prospectively quantify the occurrence of SECI using magnetic resonance imaging (MRI) in interventional radiology procedures.

Study objective

The main objective of this study is to detect occurrence of SECI after trans-radial access in interventional radiology procedures. The secondary objective is to determine if there is a difference in the incidence of silent stroke after approach through the left or the right radial artery.

Study design

Observational study.

Study burden and risks

Subjects will undergo a MRI study consisting of a DWI, T2W and a FLAIR sequence. No contrast agent will be given. There is no significant health risk or suspected benefit in MR imaging. This MRI will be performed within three days after the interventional radiology procedure. No additional hospital visits are required. Some patients experience claustrophobia during MR imaging, possibly causing physiological discomfort.

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

Informed consent
Age > 18 years old
Scheduled for either:
Transarterial chemo embolization (TACE)
Transarterial radio embolization (TARE; both Y90 admission as Y-90 pre-treatment angiography)
Angioplasty or stent placement in the mesenteric or renal
Embolization of the renal, hepatic, splenic of mesenteric arteries

Exclusion criteria

Contra-indication for MRI (including claustrophobia)
Radial artery diameter: <1.8 mm
Barbeau type D (insufficient palmar arch)
Not able to given written informed consent
Hemodynamically unstable patients
History of stroke or transient ischemic attack (TIA)
Legally incompetent adults
insufficient command of the Dutch language.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2020
Enrollment:	107
Type:	Anticipated

Ethics review

Approved WMO Date:	31-01-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL70647.078.19