

Prevention of intimal injury during transradial coronary intervention

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28253

Source

NTR

Brief title

RAILWAY trial

Health condition

Radial artery, injury, sheathless arterial access

Sponsors and support

Primary sponsor: Landsteiner Institute

Source(s) of monetary or material Support: Bronovo Research Foundation

Intervention

Outcome measures

Primary outcome

Intimal injury detected by radial artery OCT

Secondary outcome

- The primary endpoint stratified by localization of the injury:
- Procedural progress:
- Patient's comfort
- The occurrence of radial artery occlusion (RAO)

Study description

Background summary

This study will explore the burden and extent of vascular damage after transradial coronary angiography. Patients without transradial arterial access in the past will be randomized to a sheathless procedure or access using an arterial sheath. After the procedure, vascular injury will be assessed by optical coherence tomography.

Study objective

Compared to transradial access through a vascular sheath, a sheathless system will prevent vascular injury of the radial artery

Study design

-Initial procedure and 1 month follow up

Intervention

Use of a sheathless system

Contacts

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Eligibility criteria

Inclusion criteria

- Admitted for transradial coronary angiography with option to ad-hoc coronary intervention
- Older than 18 years
- Able and willing to give informed consent

Exclusion criteria

- Severe renal dysfunction (eGFR < 30ml/min)
- Previous TRA through the same radial artery
- Intervention for ST elevation myocardial infarction
- Admitted for work-up valve disease (except TAVI)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control: Active

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 19-01-2018
Enrollment: 50
Type: Anticipated

Ethics review

Positive opinion
Date: 10-03-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44272
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6894
NTR-old	NTR7081
CCMO	NL62851.098.17
OMON	NL-OMON44272

Study results