RADial Access Research: echo based radial artery evaluation for diagnostic and therapeutic coronary procedures

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To assess structural changes in the radial artery wall 3 hours and 30 days after catheterization with a 6 F sheath for diagnostic or interventional coronary procedures and elucidate arterial healing patterns that might explain early radial artery...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39220

Source
ToetsingOnline

Brief title
RADAR

Condition

- Coronary artery disorders
- Vascular injuries

Synonym
radial artery spasm and occlusion

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: Radial Artery, radial artery occlusion, very high resolution ultrasound

Outcome measures

Primary outcome

Assessment of arterial wall healing after radial artery cannulation with a 6F sheath.

Secondary outcome

Can arterial wall healing patterns after radial artery cannulation predict post-procedural radial artery spasm, late radial artery occlusion and/or loss of radial pulse?

Study description

Background summary

Invasive diagnostic angiography and percutaneous coronary intervention (PCI) are essential pillars in contemporary cardiology. Patients with a wide spectrum of clinical presentations from stable angina to unstable coronary syndromes including acute ST-elevation myocardial infarctions are exposed to these kinds of procedures. Since its introduction in 1977 multiple iterations have refined the PCI technique into a safe procedure with low clinical adverse event rates. For years the common femoral arteries were the access site of first choice for these invasive procedures. Sheath size, anti-thrombotic regimen, acuity and patient related characteristics (vessel size, obesity, gender*) have been identified as predictors for procedure related vascular complications. Vascular complications, bleeding complications and need for Red Blood Cell transfusions are linked to short and longer-term mortality. The radial artery is an alternative access site with less vascular and bleeding complications. After confirmation of ulnar artery patency suggesting an intact palmar arterial arch (with the Allen*s test) the radial artery is eligible for catheterization. However coronary diagnostic and interventional procedures through radial access can be more challenging. In up to 5-10% of radial cases the procedure needs to be aborted with cross-over to the femoral route because of radial artery spasm. Late radial artery occlusion occurs in 0.6 to 12% of cases potentially leading

to functio laesa of the hand involved.

Study objective

To assess structural changes in the radial artery wall 3 hours and 30 days after catheterization with a 6 F sheath for diagnostic or interventional coronary procedures and elucidate arterial healing patterns that might explain early radial artery spasm, late radial artery occlusion or loss of radial artery pulsation precluding future arterial punctures and sometimes leading to localized pain and functional impairment.

Study design

This is a single-center prospective observational study, which will include approximately 100 patients who will undergo a diagnostic or interventional coronary procedure through radial artery access.
After enrolment in the study protocol patients will undergo two-dimensional vascular imaging and color Doppler ultrasonic assessment with a Siemens 7-10Mhz linear probe and with the very-high resolution ultrasound Visualsonics Vevo® 2100 echo machine and a Visualsonics MS550D 22-55 Mhz probe. The rationale to use the very high resolution device is to obtain advanced and detailed imaging of the radial artery wall which is not reliably imaged by conventional high resolution echo systems.

Two experienced technicians (JL and KW) will perform the ultrasound examinations at baseline before radial artery cannulation, 3 hours after arterial sheath removal and 4-6 weeks after the procedure. Whenever clinically indicated, follow up visits and additional imaging will be organized.
A pre-specified battery of measurements will be prospectively collected in a dedicated database.

At each time point a clinical assessment will be performed to assess the puncture site specifically focusing on presence of
• any subjective discomfort
• functional impairment
• radial pulse.

Study burden and risks

All patients who participate in the study will undergo a non-invasive echographic assessment of the radial artery before the procedure, 3 hours after catheter removal and 30 days after the procedure. The echo assessment takes approximately 20 minutes.

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

All patients who will undergo a radial procedure performed by the interventional cardiologist experienced in radial access,are eligible for the study if other inclusion/exclusion criteria are fulfilled..
Inclusion:
1) > 18 years
2) Signed informed consent

Exclusion criteria

1) No informed consent
2) Previous radial artery catheterization

3) STEMI

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	29-12-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	09-09-2013
Application type:	Amendment
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	NL37806.078.11