# Reduction compression period of the arteria radialis after diagnostic cardiac catheterization.

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To describe the differences in safety, patient comfort and admission period after diagnostic cardiac catheterization through radial access, between the current protocol and the protocol of fast desufflation by Carrington et al.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Vascular therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37353

**Source**
ToetsingOnline

**Brief title**
Reducing arteria radialis compression time

### Condition

- Vascular therapeutic procedures

**Synonym**
Radial artery; pressure

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Arteria radialis, Cardiac catheterization, Compression, Terumo TR-band

## Outcome measures

### Primary outcome

Bleeding, defined as arterial (pulsatile) high velocity flow from the puncture

site

### Secondary outcome

Oozing from the puncture site, defined as non-pulsatile.low velocity blood flow

Occlusion of the radial artery

Swelling at the puncture site

Patient comfort, measured on the visual-analog scale (VAS)

Time between return on the short-stay unit and discharge, in minutes

Incidence of cross-over from study group to control group.

# Study description

### Background summary

To obtain arterial access for a diagnostic cardiac catheterization or percuteneous coronairy intervention (PCI) the cardiologist can choose between the arteria femoralis and the arteria radialis. In the University Medical Center Groningen the arteria femoralis is commonly used. After intervention the puncture site is closed with an arteriotomy closure device (ACD). Patients after radial access receive a pressure bandage at the puncture site, usually the Terumo (TR) wrist bandage.

The bedrest period for patients with an ACD is 1 hour after diagnostic cardiac catheterization and 2 hours after PCI. After the bedrest period patients are discharged 1 hour after diagnostic procedures or 4 hours after PCI. This to observe potential bleeding complications after the procedure.
In patients with radial access, the TR bandage will be removed according to current protocol after 4 hours and additionally 1 hour observation is required.

Serveral cardiologists have the intention to use the arteria radialis more frequent for cardiac catheterization or PCI. In a meta-analasys radial access is related to a 73% decrease in major bleeding complications compared to femoral access. Also there are no significant differences in MACE. Evenso there are no differences in succes percentage for cardiac cathetrization or PCI and admission time is shorter for radial access (Am Heart J. 2009 Jan;157(1):132-40).

Admission time for diagnostic cardiac catheterization at the short-stay unit is in case of femoral access with an ACD approximately 2 hours. For patients after radial access post procedural admission time is approximately 5 hours. To guarantee patient throughput, uniformity of care and more efficient use of capacity of the short-stay unit, patients after radial access should not have a longer hospital admission time than patients after femoral access. Carrington et al. (J Interv Cardiol. 2009 Dec;22(6):571-5) have shown that it is safe to deflate the TR wrist band faster than four hours.

### Study objective

To describe the differences in safety, patient comfort and admission period after diagnostic cardiac catheterization through radial access, between the current protocol and the protocol of fast desufflation by Carrington et al.

### Study design

Single-center prospective randomised cohort study.

### Intervention

Two groups:
Control group receives standard care:
- TR band fully inflated for two hours
- at two hours, deflate with 2 mls
- at three hours, deflate with 2 mls
- at fours hours, fully deflate in one minute

Experimental group:
- TR band fully inflated for one hour
- at one hour, start deflating with 2 mls every ten minutes until complete deflation, which should be obtained within 60-70 minutes.

Both groups remain one hour at the unit for observation of the wrist.

### Study burden and risks

This study does not lead to extra burden for the patient. The risk is limited

to bleeding at the puncture site. This will be observed directly and treated immediately by inflating the wrist band until bleeding ceases. This leads to a prolonged period of radial compression time, but it should be noticed that this risk is also present for patients in the control group.

In case of repeated bleeding (at two consecutive attempts to lower the pressure in the TR band) patients will cross-over to the control group.

## 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

Diagnostic cardiac catheterization through radial artery, patients admitted to short stay unit

### Exclusion criteria

INR>2.0; percutaneous coronary intervention (PCI); cross-over to femoral artery; bleeding disorder

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Health services research

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 19-11-2012 |
| Enrollment: | 174 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 24-07-2012 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## 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 | NL38454.042.11 |