Conventional vascular closure device vs Statseal hemostasis: Comparing the effects on hand sensibility for radial hemostasis

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28346

Source
Nationaal Trial Register

Brief title
CONVALESCENT

Health condition

Diminished hand sensibility after transradial access heart catheterisation

Sponsors and support

Primary sponsor: None yet.
Source(s) of monetary or material Support: In progress

Intervention

Outcome measures

Primary outcome

Prevention of diminished hand sensibility after transradial access by shorter wrist

compression time using Statseal hemostasis.

Secondary outcome

Evaluation of the effect of shorter wrist compression time on hand function (questionnaires and grip testing)
Prevention of bleeding complications and hematomas

Study description

Background summary

Rationale: Radial artery access has become today´s preferred method of approach during coronary intervention. Previous research showed an association between transradial approach (TRA) and diminished hand sensibility. Compression neuropathy of the superficial radial nerve (SRN) by the vascular closure device (VCD) may be the cause of this effect. The use of Statseal discs, containing a combination of hydrophilic polymer and potassium ferrate, significantly decreases hemostasis time.. Shorter compression time of the VCD could lead to a significant reduction in loss of hand sensibility.
Objective: To prevent loss of hand sensibility by using Statseal discs during post-TRA hemostasis.
Study design: This is a multi-center, randomized clinical trial. Patients will be randomized to conventional hemostasis using only a VCD and hemostasis by using both the VCD and a Statseal disc. Hand sensibility of both hands will be tested using the Semmes-Weinstein Monofilaments test and hand function of both hands will be evaluated through validated questionnaires and grip tests. Results will be compared before and 1 month after the procedure in both groups
Study population: Patients planned for diagnostic coronary angiography will be asked for participation. Major exclusion criteria are previous coronary catheterization and previous lower limb surgery.
Main study endpoints: Diminished hand sensibility 1 month after TRA comparing , change in self-reported hand function and reduced manual and pinch grip strength.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will answer a short questionnaire about hand function before the procedure and after 1 month. Patients will undergo a painless Semmes-Weinstein Monofilaments test and a painless manual and pinch grip test before the procedure and after 1 month. The investigational product (Statseal hemostasis disc (SHD)) is expected to allow shorter hemostasis time and earlier discharge from the hospital. Despite the theorized accelerated blot clotting by Statseal use, the shorter compression time may cause a higher incidence of post intervention bleeding and hematomas

Study objective

Shorter wrist compression time through combined hemostasis will see a reduction of

diminished hand sensibility after transradial acces catheterisation

Study design

Before and one month after catheterisation

Intervention

To compare hemostasis after transradial access by using Statseal and 60 minutes of applied pressure by vascular closing device to 2 full hours of applied pressure by the vascular closing device without using Statseal.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients admitted for transradial coronary angiography
- Older than 18 years
- Able and willing to give informed consent

Exclusion criteria

- Previous TRA through the same radial artery
- Previous upper limb surgery

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2019
Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7748
Other	METC Zuidwest Holland : in progress

Study results