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

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Prevention of diminished hand sensibility (and secondary: hand function) after trans radial access coronary angiography by shorter wrist compression time using Statseal hemostasis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Administration site reactions
Study type	Interventional

Summary

ID

NL-OMON52480

Source
ToetsingOnline

Brief title
The CONVALESCENT trial

Condition

- Administration site reactions
- Peripheral neuropathies
- Cardiac therapeutic procedures

Synonym
Hand function disorders, peripheral neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: AngioCare; BioLife; researchgroep HAGA; wetenschapsfonds HMCziekenhuis,HagaZiekenhuis

Intervention

Keyword: Angiography, Heart catheterization, Hemostasis, Radial access, Statseal

Outcome measures

Primary outcome

The occurrence of diminished hand sensibility after TRA as measured by the

Semmes-Weinstein monofilaments score before and 1 month after intervention.

Secondary outcome

- Perceived hand function disorders as measured in the The Disabilities of the

Arm, Shoulder and Hand Score (Quick DASH score) and Cold Intolerance Symptom

Severity score (CISS score) before and 1 month after intervention.

- Objectified hand strength disorders as measured in the pinch and manual grip

(PMG) tests.

- Bleeding complications as defined as any blood loss from the trans radial

access site after hemostasis which requires additional usage of vascular

closure device.

Study description

Background summary

Radial artery access has become today*s preferred method of approach during coronary intervention. Previous research showed an association between transradial approach and diminished hand sensibility. Compression neuropathy of the superficial radial nerve by the vascular closure device 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 wrist compression time by the vascular closure device could lead to a significant reduction in loss of hand sensibility.

Study objective

Prevention of diminished hand sensibility (and secondary: hand function) after trans radial access coronary angiography by shorter wrist compression time using Statseal hemostasis.

Study design

This is a multicenter, randomized, interventional open label trial with a prospective design. The endpoints assessment will be blinded. The protocol of the trial will be registered at the Netherlands Trial Register (https://www.trialregister.nl/) (NL7748). Two centers (The Haaglanden Medisch Centrum hospital and the HAGA hospital, both in the Hague) will screen patients for the study. During the inclusion period of 6 months, we expect to have screened a total of 1700 patients. All patients admitted for coronary angiography will be evaluated for in- and exclusion criteria. We expect to screen 8 patients per day per center. At least half of them will meet exclusion criteria. Of these 850 patients, we expect 30% of them to be willing to participate in the study. They will be randomized to Statseal hemostasis (SSH) or conventional hemostasis (CH) in a 1:1 fashion.

Intervention

After trans radial catheter access, we will compare conventional hemostasis by 2 full hours of applied pressure by the vascular closure device to combined hemostasis using Statseal Advanced Disc application and 60 minutes of applied pressure by the VCD.

The Statseal* Advanced Disc is a topical hemostat that forms an occlusive seal to stop the flow of blood and exudates. Comprised of a hydrophilic polymer and potassium ferrate,. Statseal works independently of the clotting cascade to seal the site. It is shaped like a patch and placed under the VCD on top of the radial access site.

After the transradial procedure the sheath will be retracted for 2-3 cm. Hereafter the Statseal will be placed in position and covered by a transparent patch. After placing the vascular closure device in position, the sheath will be retracted completely while insufflating the VCD with 8 cc of air. In the SSH protocol the VSD will be applied for 60 minutes.

Intervention cardiologists of the two centers will perform all interventions.

Preferably 6FR guiding catheters are used but ultimately catheterization strategy will be left to the discretion of operator. Post intervention care and admittance of hemostasis protocol will be performed by trained research nurses.

Study burden and risks

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. Echo doppler will be performed on all treated radial arteries.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.

Contacts

Public
Haaglanden Medisch Centrum

Lijnbaan 32
Den Haag 2512 VA
NL
Scientific
Haaglanden Medisch Centrum

Lijnbaan 32
Den Haag 2512 VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients admitted for trans radial access 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:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-02-2021
Enrollment:	250
Type:	Actual

Medical products/devices used

Generic name:	Hydrophilic polymer and potassium ferrate topical hemostat patch.
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-11-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL69957.098.19