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

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Shorter wrist compression time through combined hemostasis will see a reduction of diminished hand sensibility after transradial acces catheterisation

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28346

Bron
Nationaal Trial Register

Verkorte titel
CONVALESCENT

Aandoening

Diminished hand sensibility after transradial access heart catheterisation

Ondersteuning

Primaire sponsor: None yet.
Overige ondersteuning: In progress

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Prevention of diminished hand sensibility after transradial access by shorter wrist compression time using Statseal hemostasis.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

Shorter wrist compression time through combined hemostasis will see a reduction of diminished hand sensibility after transradial acces catheterisation

Onderzoeksopzet

Before and one month after catheterisation

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7748
Ander register	METC Zuidwest Holland : in progress

Resultaten