RCT incisional NPWT versus sterile surgical dressing for surgical wounds after arterial vascular surgery

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Null hypothesis: There is no differences in amount and seriousness of wound complications between the INPWT and SSD wound application technique after vascular surgery at the groin.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26008

Bron
Nationaal Trial Register

Verkorte titel
Prevenastudie

Aandoening

Patient who underwent arterial vascular surgery with surgical incision at the groin.

gesloten liesincisie na arteriële vaatchirurgie vanwege PAOD

Ondersteuning

Primaire sponsor: Medical Centre Haaglanden
Overige ondersteuning: Medical Centre Haaglanden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence of wound complications such as wound infection, wound dehiscence, seroma leak and wound necrosis.

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY

Rationale:

Complications after vascular arterial surgery are common and can be very serious. They prolongs hospital stay and increases costs. In the Haaglanden Medical Centre both Incisional Negative Pressure Wound Therapy (INPWT) and Sterile Surgical Dressing (SSD) are used as post-operative dressings. There is growing evidence that INPWT might prevent surgical wound complications, which will promote patients wellbeing and decrease costs.

Objective:

Primary Objective: to investigate if INPWT will prevent wound complications such as wound dehiscence, wound infection, seroma leakage and wound necrosis after arterial vascular surgery. Secondary Objective(s): to investigate if INPWT will prevent additional surgery, prolonged hospital stay, re-admissions and extra visits to the outpatient clinic and thereby and reduce costs.

Study design:

A prospective randomized controlled clinical trial of two different postoperative wound treatments.

Study population:

All patients that underwent vascular arterial surgery with one or more groin incisions. Except patients for Endovascular Abdominal Repair (EVAR).

Intervention (if applicable):

Incisional Negative Pressure Wound Therapy (Prevena ®) or sterile surgical dressing (Curapor®).

Main study parameters/endpoints:

Wound complications such as SSI, wound dehiscence, seroma leak and wound necrosis and complete wound healing.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Both therapies are standard and safe therapies and will not harm patients. Additional there will be no extra burden for the patients.

Doel van het onderzoek

Null hypothesis:

There is no differences in amount and seriousness of wound complications between the INPWT and SSD wound application technique after vascular surgery at the groin.

Onderzoeksopzet

1,2,4 after surgery and date complete wound healing

Onderzoeksproduct en/of interventie

Incisional Negative Pressure Wound Therapy for surgical closed incision (Prevena)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients age above 18 year

• Mentally competent in order to give informed consent

• Undergo one of the following surgical procedures:

- Bypass: aortic-iliacal, ilical-femoral, femoral-femoral, femoral-popliteal, femoral-crural, femoral-tibial

- Endarterectomy: iliacal, femoral

- Reconstruction aneurysm: femoral

- Embolectomy iliacal, femoral

• Patients must be fit for surgery (regardless age or co-morbidities such as diabetes or obesity)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Patients age younger than 18 year

• Endovascular aortic procedures (EVAR with transverse groin incisions)

• Aortic abdominal and thoracal procedures

• Arterial surgical procedures of upper extremities

• Allergy for the product such as acrylic adhesive coating or silver

• Unable to provide informed consent

• Unable to understand the Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-05-2017
Aantal proefpersonen:	270
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-06-2017
Soort:	Eerste indiening

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	NL6307
NTR-old	NTR6481
Ander register	METC 17-017 : HMC 2016-3615

Resultaten