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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26008

Source
Nationaal Trial Register

Brief title
Prevenastudie

Health condition

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

gesloten liesincisie na arteriële vaatchirurgie vanwege PAOD

Sponsors and support

Primary sponsor: Medical Centre Haaglanden
Source(s) of monetary or material Support: Medical Centre Haaglanden

Intervention

Outcome measures

Primary outcome

Incidence of wound complications such as wound infection, wound dehiscence, seroma leak

and wound necrosis.

Secondary outcome

Complete wound healing percentages and time till complete wound healing. Hospital stay in days, additional surgery, re-admissions, extra visits to the outpatient clinic in numbers.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

• 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)

Exclusion criteria

• 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2017
Enrollment:	270
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-06-2017
Application type:	First submission

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

Study results