Randomized Clinical Trial incisional NPWT versus sterile surgical dressing for surgical wounds after arterial vascular surgery

Published: 24-03-2017
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Primary Objective: to investigate if INPW will reduce wound complications such as wound dehiscence, wound infection (SSI), seroma leak and wound necrosis after arterial vascular surgery.Secondary Objective(s): to investigate if INPWT will prevent...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON47828

Source
ToetsingOnline

Brief title
RCT INPWT vs SSD

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
Incisional vacuum therapy, INPWT

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum

Source(s) of monetary or material Support: materialen worden betaald vanuit het afdelingsbudget.

Intervention

Keyword: RCT INPWT vs SSD

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

In general there is evidence that INPWT will reduce wound complications however data in vascular studies present inconclusive results regarding the reduction of wound complications after vascular surgery and more specific the reduction of wound dehiscence. However due to the high number of wound complications in our recent study it is important to look for a management which will reduce those complications. Therefore the current study will investigate if INPWT will reduce wound complications compared with sterile surgical dressing(SSD).

Study objective

Primary Objective: to investigate if INPW will reduce wound complications such as wound dehiscence, wound infection (SSI), seroma leak 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.
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

The study design is a prospective observational Randomized Clinical Trial. Due to the nature of the treatments blinding is not possible.

Study burden and risks

Since this study compared to existing therapies, there is no risk of harm to the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Bypass: aortic-iliacal, ilical-femoral, femoral-femoral, femoral-popliteal, femoral-crural, femoral-tibial
• Endarterectomy: iliacal, femoral
• Reconstruction amorism: femoral
• Embolectomy iliacal, femoral

Exclusion criteria

Endovascular aortic procedures iliacal (groin incision)
Aortic abdominal and thoracal procedures
Arterial surgical procedures of upper extremities
Silver allergy

Study design

Design

Study type:	Observational non invasive
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):	15-05-2017
Enrollment:	270
Type:	Actual

Medical products/devices used

Generic name:	Incisional negative pressure wound theray
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	09-04-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	21-04-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL60311.098.17

Study results

Date completed:	06-01-2023
Actual enrolment:	291