Negative pressure wound therapy for surgical wounds of the foot and ankle

Published: 04-01-2016
Last updated: 19-04-2024

Primary Objective: The primary objective of this study tTo determine the feasibility ofreduce the amount of surgical site infections using prophylactic NPWT in patients undergoing surgery to the foot and/or ankle. The NPWT device which we will use...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON46335

Source
ToetsingOnline

Brief title
NEWTON-trial

Condition

- Fractures
- Skin and subcutaneous tissue disorders
- Bone and joint therapeutic procedures

Synonym
postoperative woundinfection, Surgical site infection

Research involving
Human

Sponsors and support

Primary sponsor: Chirurgie
Source(s) of monetary or material Support: Ministerie van OC&W,Smith&Nephew, Inc

Intervention

Keyword: ankle, foot, Negative pressure, Surgery

Outcome measures

Primary outcome

(1) surgical site infections as classified by the Centers for Disease Control

and Prevention

Secondary outcome

(1) AOFAS

(2) Range of motion

(3) VAS

(4) Quality of Life

(5) Patient satisfaction

Study description

Background summary

Rationale: By applying prophylactic Negative Pressure Wound Therapy (NPWT) to patients undergoing surgery to the foot and/or ankle a reduction in the amount of postoperative woundsurgical site infections will be achieved.

Objective: The aim of this study to To determine the feasibility effect of using prophylactic NPWT in patients undergoing surgery to the foot and/or ankle.

Study design: The study will be a sSingle-center feasibility intervention study.

Study population: The study population will consist of pPatients * 18 and *80 years undergoing foot and ankle surgery.

Intervention (if applicable): The intervention groupAll patients will receive NPWT directly following surgery for at least one week. Longer NPWT can be applied when necessary.

Main study parameters/endpoints: The main study parameterend point is the amount of surgical site infections. These will be diagnosed and classified trough the US Center for Disease and Control and Prevention (CDC) criteria.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Surgery to foot and/or ankle is associated with high complication rates. A well-known treatment of these complications such as surgical site infections is NPWT. We would like to investigate the feasibility effect of applying prophylactic NPWT to patients undergoing surgery to foot and/or ankle. By doing so we hope to reduce the amount of complications following surgery and improve outcome.

Future perspective: If NPWT turns out to be effectivefeasible in this study population, the results will be used to set up a randomized controlled trial on prophylactic use of prophylactic NPWT in foot and ankle surgery.

Study objective

Primary Objective: The primary objective of this study tTo determine the feasibility ofreduce the amount of surgical site infections using prophylactic NPWT in patients undergoing surgery to the foot and/or ankle. The NPWT device which we will use for this pilot has not been used in foot/ankle surgery yet. We therefore aim to test this new wearable device prior to a RCT.

Secondary Objectives: Secondary objective are (1) To improve functional outcometo reduce the amount of post-operative wound infections following foot and ankle surgery; (2) to reduce the amount of pain post-operatively (3) to regain maximum range of motion earlier compared to the current standard therapy and (4) to reduce the amount of costs associated with post-operative woundsurgical site infections following foot and ankle surgery by applying negative pressure wound therapy to closed incisionsand (5) improve quality of life by foregoing surgical site infections.

Study design

single-center, intervention study

Intervention

(1) prophylactic application of a NPWT device

Study burden and risks

Patient risks in this study are minimal and acceptable as negative pressure wound therapy is a concept which has been studied extensively before. In these studies a beneficial effect of NPWT over regular wound dressings has been

shown.

Contacts

Public
Selecteer

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Selecteer

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients *18 and * 80 years
* Surgery to the foot and/or ankle

Exclusion criteria

* Open fractures
* Antibiotic treatment at the time of the operation for a concomitant disease or infection

* Insufficient comprehension of the Dutch language
* Patients with immune-deficiencies
* Inability to address NPWT
* Incision < 3 cm

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2016
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Negative pressure wound therapie
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-01-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	16-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL55242.018.15