Proof-of-principle Demonstration and Safety Testing of Reduced Dressing Changes in a Negative-Pressure Wound Therapy Device with Instillation.

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To proof the instillation technique prevents foam ingrowth and obstruction and investigate patient safety and comfort when reducing dressing changes in negative-pressure therapy with instillation.

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

Summary

ID

NL-OMON43226

Source
ToetsingOnline

Brief title
NPWTi Safety Study

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
wound healing

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Instillation, Negative Pressure Therapy, Safety, Wound healing

Outcome measures

Primary outcome

Efficacy, patient safety and comfort will be evaluated by the investigator and an experienced wound consultant during dressing changes. Primarily by evaluating ingrowths of foam.

Secondary outcome

Patient safety and comfort will be evaluated by the investigator and an experienced wound consultant during dressing changes. Secondary by evaluating erythema of periwound skin, patients' clinical status, fluid collection beneath the dressing or other disruption of the dressing, occurrence of medical device failure and patient experience.

Study description

Background summary

Negative pressure wound therapy is an esteemed and effective form of wound treatment. Following current standard protocol the bandage is renewed twice per week. This is both time-consuming and stressful for the patient and health care professional. A new device combines negative pressure with an instillation system reducing ingrowth and adhesion of tissue in the used foam and dressings. Suggesting dressing changes could be reduced to once per week.

Study objective

To proof the instillation technique prevents foam ingrowth and obstruction and investigate patient safety and comfort when reducing dressing changes in

negative-pressure therapy with instillation.

Study design

A prospective observational case series that will be performed at the Radboud University Medical Center Nijmegen, with a sample size of n=5.

Intervention

All subjects will be treated with negative-pressure wound therapy with instillation and have their dressings changed once a week.

Study burden and risks

Included patients could directly benefit from participation in the study; dressing changes are time consuming and sometimes painful. Reducing the amount of changes can be described as a benefit.
Based on our experience with the NPWT with instillation technique thus far we do not expect any risks for patients* health or wound healing. However minor delay in wound healing or slightly increased painful dressing changes can not be excluded.
Based on the above, our estimation is that in our study there is a small chance (*kleine kans*) of slight damage (*lichte schade*) and therefore a small risk (*verwaarloosbaar risico*) according to the risk classification of the *Nederlandse Federatie van Universitair Medische Centra* (NFU).

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Trauma patient who is at least 18 years old on the day the informed consent form will be signed.
2. Patient has an open wound with major skin tissue loss.
3. The wound can not be primarily closed and negative-pressure wound therapy is indicated.
4. The expected duration of treatment with negative-pressure wound therapy is at least two weeks.
5. Patient scores I to III in the American Society of Anesthesiologists physical status classification system (ASA I-III).
6. Patient provides informed consent.
7. Patient is willing and able to comply with the trial protocol.

Exclusion criteria

1. Open wounds with exposed blood vessels, evidence of ischemia, necrotic tissue requiring further débridement, infection or osteomyelitis.
2. Patients not treated in the RadboudUMC.
3. Pregnant women.
4. Patient has (a history of) a (chronic) pain syndrome that interferes with the interpretation of the pain score results.
5. Patient is or turns out to be allergic to one of the materials used in negative-pressure wound therapy.
6. Wounds in body surface areas that are technically difficult for applying negative-pressure wound therapy (i.e. on feet or around an external fixator).
7. Wounds with exposed organs.
8. Patient is unable to provide informed consent.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2016
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	14-11-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL59157.091.16