# Faster wound healing with topical negative pressure therapy in difficult to heal wounds

Submission date	Recruitment status	Prospectively registered
31/05/2009	No longer recruiting	[_] Protocol
<b>Registration date</b>	Overall study status	[] Statistical analysis plan
24/07/2009	Completed	[] Results
Last Edited	Condition category	Individual participant data
24/07/2009	Injury, Occupational Diseases, Poisoning	[_] Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

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# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 2003-263 CMO

# Study information

#### Scientific Title

Faster wound healing with topical negative pressure therapy in difficult to heal wounds: a prospective randomised controlled trial

#### **Study objectives**

This study aimed to investigate the effectiveness and safety of topical negative pressure therapy, compared with conventional dressing therapy in patients with difficult to heal wounds of various aetiologies and particularly in spinal cord injury (SCI) patients with pressure ulcers.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Committee on Research Involving Human Subjects, Arnhem Nijmegen approved on the 24th January 2003 (ref: 2003-263 CMO)

**Study design** Prospective stratified randomised controlled trial

**Primary study design** Interventional

Secondary study design Randomised controlled trial

**Study setting(s)** Hospital

## Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

Difficult to heal wounds of various aetiologies

#### Interventions

Patients randomly assigned to topical negative pressure therapy received a treatment with the VAC-system<sup>™</sup> (Vacuum-Assisted Closure; KCI USA, San Antonio, TX, USA). According to manufacturer's instructions for use, the foam dressings and the TRAC Pad® were changed three times a week (Monday morning, Wednesday and Friday in the afternoon). The fluid connection system was changed at least once a week. Patients randomly assigned to the control group received treatment with a sodium hypochlorite 0.25% solution. This wet-to-moist dressing was changed two to three times a day, depending on the wound debris.

#### Intervention Type

Other

**Phase** Not Applicable

#### Primary outcome measure

Time to 50% wound volume reduction, with a maximum follow-up time of six weeks. This point was determined by measuring the difference between the weekly measured wound volume and the initial wound volume before treatment.

#### Secondary outcome measures

1. Wound healing failure rates, defined as any deterioration of the wound that necessitated changing the treatment protocol to which patient was assigned

2. Any adverse event, defined as any unfavourable and unintended diagnosis, symptom, sign, syndrome, or disease that either arose during the study, or seemed to deteriorate, if present at baseline

Wound healing failure and adverse events were only diagnosed as such after confirmation by an independent physician.

#### Overall study start date

01/03/2003

#### **Completion date**

01/03/2005

# Eligibility

#### Key inclusion criteria

1. Aged greater than or equal to 18 years, either sex

2. Difficult to heal surgical wounds (i.e. dehisced abdominal wounds, complex pilonidal sinus, infected wounds and pressure ulcers)

3. Paraplegic and tetraplegic patients with pressure ulcers grade IV according to the European Pressure Ulcer Advisory Panel grading system

#### Participant type(s)

Patient

#### **Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

Target number of participants

24

#### Key exclusion criteria

1. Untreated osteomyelitis

- 2. A life expectation less than one year
- 3. Radiation or chemical exposure
- 4. Pregnant or lactating females
- 5. Not able to comply to one of the interventions
- 6. Treated with one of the study treatments in the past 30 days

# Date of first enrolment

01/03/2003

Date of final enrolment 01/03/2005

## Locations

#### **Countries of recruitment** Netherlands

**Study participating centre Radboud University Nijmegen Medical Centre** Nijmegen Netherlands 6500 HB

## Sponsor information

**Organisation** Radboud University Nijmegen Medical Centre (Netherlands)

#### Sponsor details

690 Department of Surgery PO Box 9101 Nijmegen Netherlands 6500 HB +31 (0)2 436 16 421 H.vanGoor@CHIR.umcn.nl

**Sponsor type** Hospital/treatment centre

#### Website

http://www.umcn.nl/scientist/afdelingen/heelkunde?actieve\_tab=scientist

ROR https://ror.org/05wg1m734

# Funder(s)

**Funder type** Hospital/treatment centre

**Funder Name** Radboud University Nijmegen Medical Centre (Netherlands)

# **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary** Not provided at time of registration