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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
Registration date	**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

Contact name
Dr Erik de Laat

Contact details
Radboud University Nijmegen Medical Centre
926 Plastic Surgery
PO Box 9101
Nijmegen
Netherlands
6500 HB
+31 (0)6 533 55 278
e.delaat@plchir.umcn.nl

Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
Prospective stratified randomised controlled trial

Study type(s)
Treatment

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™ (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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Radboud University Nijmegen Medical Centre (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration