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A pilot randomised controlled trial of topical negative pressure therapy for grade III/IV pressure ulcers

Submission date
17/03/2008

Recruitment status
No longer recruiting

Registration date
31/10/2008

Overall study status
Completed

Last Edited
21/08/2015

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pressure ulcers (also called bed sores) are wounds which can take a long time to heal. They are very painful and can have a severe effect upon a patient's daily life. Negative pressure wound therapy (NPWT) is one type of treatment available for treating pressure ulcers. This treatment works by applying a suction force via a foam dressing to the wound. The liquid from the wound is then collected in a canister. NPWT is thought to heal wounds faster and reduce wound infection compared to standard treatments. NPWT is widely used within the National Health Service (NHS), even though there has not been enough research done to find out whether this treatment actually works or not. The best way to find out if a treatment works is by doing a study. Patients are randomly put into two groups: one group will receive the new treatment and the other group will receive the usual treatment. We can then compare the two groups of patients to find out if there are any differences, which will be due to the treatment they received. Trials are very expensive to run and need careful planning. Before doing a large trial to find out if NPWT is an effective treatment for pressure ulcers, we first needed to conduct a small pilot trial. This was to give us the information we need to understand whether we need to do a larger, more expensive trial and if so, how that trial should be designed.

Who can participate?
This trial recruited patients at least 18 years of age and who had at least one severe pressure ulcer, who were being treated within Leeds Primary Care Trust and, in their treating clinician's opinion, able to receive NPWT. Patients were recruited from community and hospital settings in Leeds Community Healthcare NHS Trust and Leeds Teaching Hospitals NHS Trust.

What does the study involve?
Patients with severe pressure ulcers were randomly assigned into one of two groups: one group received NPWT and the other group received a standard treatment. Participants were asked to complete health-related quality of life questionnaires at regular intervals. Nurses collected the following information from each patient:
-The treatments they received;
-How often their treatments were changed;

-The amount of pain associated with treatment changes;
-The number of hospital admissions or discharges;
-Whether the pressure ulcer healed, and
-The length of time a patient stayed in the trial for.

What are the possible benefits and risks of participating?
There were no direct benefits to patients taking part in this study. Indirectly, participants may have felt that their involvement helped others in the future with a pressure ulcer, as this study provided further information on the treatment of pressure ulcers. The treatments being evaluated in this trial were both used within the NHS. There was no evidence to suggest that any treatment is associated with a greater risk than the other. All patients were monitored for any adverse events during the trial, which were recorded and reported.

Where is the study run from?
The University of York (UK).

When is the study starting and how long is it expected to run for?
The study started in September 2008 and ended in October 2009. Patients were recruited over 12 months (September 2008 to August 2009) and then followed up for a maximum of 6 months.

Who is funding the study?
The Medical Research Council (MRC) (UK).

Who is the main contact?
Professor Nicky Cullum
nicky.cullum@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Nicky Cullum

Contact details
Department of Health Sciences
Seebohm Rowntree Building (Area 2)
University of York
York
United Kingdom
YO10 5DD

Additional identifiers

Protocol serial number
G0501814

Study information

Scientific Title
Topical negative pressure (TNP) therapy to treat grade III/IV pressure ulcers: a pilot randomised controlled trial

Study objectives
Is topical negative pressure (TNP) therapy a clinically and cost effective treatment for grade III /IV pressure ulcers?

More information can be found at: http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0501814&CaseId=6790

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern and Yorkshire Research Ethics Committee, 29/05/2008, ref: 08/H0903/22

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Grade III/IV pressure ulcers

Interventions
Participants will be randomised to receive TNP therapy or the comparator treatment (spun hydrocolloid, alginate or foam dressings). TNP therapy consists of a computer-controlled vacuum pump, into which disposable components fit. A plastic canister slots into the pump and collects wound exudate. The pressure ulcer to be treated with TNP will be filled with a foam dressing and then covered with a film with 2 - 3 cm overlap onto the surrounding skin in order to achieve a tight seal. Once sealed, the pump will be switched on and therapy will continue for at least 22 hours in a 24 hour period. The pump will be switched off prior to dressing removal /change. TNP therapy will continue for a duration decided by the patient and nurse in line with current practice. When not being treated with TNP, patients will be treated with spun hydrocolloid, alginate or foam dressings. In the comparator group, dressings will be changed every 1 - 3 days, as dictated by the treating nurse. The total duration of follow-up will be six months.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Time to complete healing of the pressure ulcer, to be assessed weekly.

Key secondary outcome(s)
1. Number of patients eligible (i.e. number meeting trial inclusion criteria)
2. Number of patients providing informed consent
3. Recruitment rates in primary and secondary care
4. Co-morbidities in recruited participants, assessed at baseline
5. Anatomical location of pressure ulcer and ulcer history, assessed at baseline
6. Incidence of wound infection at baseline
7. Pain
8. Frequency of dressing change and products used (resource use data)
9. Rates of hospital admission and discharge for study participants and discharge destination
10. Attrition rates
11. How are 12-item Short Form Health Survey (SF-12)/European Quality of Life Instrument (EQ-5D) data best collected from participants? Measured at baseline, 2 weeks, 1 month, 3 months and 6 months.
12. Amount of nurse training required in use of topical negative pressure therapy to support a trial
13. Adverse events
14. Nurses' opinions on documentation design
15. Training sessions required
16. Nurses' views of wound response impact on treatment choices

All other outcomes to be assessed in an ongoing fashion throughout the trial.

Completion date
31/08/2009

Eligibility

Key inclusion criteria
1. Participants must receive primary care via Leeds Primary Care Trust
2. Participants must have a pressure ulcer graded III or IV according to the European Pressure Ulcer Advisory Panel Grading System. The pressure ulcer should contain at least 80% viable tissue, or have a very thin layer of slough (non-viable tissue) requiring no further debridement prior to use of topical negative pressure therapy. Ulcers from any anatomical site are eligible for inclusion. The ulcer to be followed-up for the duration of the trial will be known as the reference ulcer. If more than one eligible ulcer is present, the reference ulcer will be defined as the deepest ulcer. All eligible ulcers can be treated with topical negative pressure therapy where required.
3. The patient should be receiving adequate nutrition, as assessed by the nurse providing care
4. Patient must be able to give informed consent
5. Adults (aged 18 years or over), either male or female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients who are unable to give informed consent
2. Patients with very limited life expectancy, e.g. undergoing end stage palliative care
3. Patients with active systemic infection at baseline, defined by clinical and/or laboratory assessment
4. Patients being treated with the V.A.C.® Instill™ machine
5. Patients with any of the following pressure ulcer characteristics:
5.1. Presence of undermining in the pressure ulcer cavity, precluding the use of topical negative pressure therapy (i.e. the deepest point of ulcer cannot be measured)
5.2. Necrotic tissue, eschar or necrotic bone present
5.3. Malignant tissue in the wound
5.4. Pressure ulcers close to exposed blood vessels and/or organs, anastomotic sites and/or nerves
5.5. Pressure ulcers located where, in the opinion of the treating clinician, a vacuum seal cannot be obtained. e.g. the anus

Date of first enrolment
01/09/2008

Date of final enrolment
31/08/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of York
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G0501814)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/07/2012		Yes	No