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Wound management of Open Lower Limb Fractures (WOLLF)

Submission date
23/02/2012

Recruitment status
No longer recruiting

Registration date
24/02/2012

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Fractures of the legs are extremely common injuries in both the civilian and military populations. The majority of these injuries are 'closed' i.e. the skin around the fracture is intact. However, if the fracture is 'open', such that the barrier provided by the skin is breached, then the broken bone is exposed to contamination from the environment. This may lead to infection and disability. The management of open fractures requires the removal of all contaminated tissue and washout of the wound in the operating theatre. Once the wound is clean, a dressing is applied. The standard treatment is a sterile dressing that is applied to the exposed area. Negative-pressure wound therapy (NPWT) is an alternative form of dressing where a foam is laid onto the wound which is attached to a pump which creates a partial vacuum. This negative-pressure removes blood and ooze from the area of the wound, thereby potentially reducing the risk of infection. Patients will be placed at random into one of the two wound management groups: standard versus NPWT and asked to complete questionnaires at 3, 6, 9 and 12 months following their injury. The study will provide us with information which may help improve the treatment of patients with similar injuries in the future.

Who can participate?
All patients over 16 years who present with an open fracture of the leg will potentially be eligible to take part.

What does the study involve?
All patients will be followed up carefully to make sure that their fracture is healing and there is no sign of infection. The only additional commitment we ask is for questionnaires to be completed at 3, 6, 9 and 12 months following the injury.

What are the possible benefits and risks of participating?
There are no specific risks of having one type of wound dressing or the other. The risks of the injury and the surgery are the same for both groups of patients in the study and are the same as for patients who are not taking part in the study. Both standard dressings and suction dressings are used across the NHS for patients with an open fracture of the leg so there is no specific advantage to you for taking part in the study. However, the information we get from this study may help us to improve treatment for future patients with similar injuries.

Where is the study run from?
Warwick Clinical Trials Unit at the University of Warwick coordinates the study and over 20 hospitals across the country are taking part.

When is the study starting and how long is it expected to run for?
April 2012 to March 2017

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Miss Jaclyn Brown
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Study website
http://www.warwick.ac.uk/go/WOLLF

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1; HTA 10/57/20

Study information

Scientific Title

A randomised controlled trial of standard wound management versus negative pressure wound therapy in the treatment of adult patients with an open fracture of the lower limb

Acronym
WOLLF

Study objectives
There is no difference in the Disability Rating Index score (DRI) one year post-injury between adult patients for an open fracture to the lower limb treated with standard wound dressings versus negative pressure wound therapy before definitive wound closure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coventry Research Ethics Committee, 06/02/2012, ref: 12/WM/0001

Study design
Multicentre 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Open fractures of the lower limb

Interventions
Standard dressing.
The standard dressing for open fractures comprises a non-adhesive layer applied directly to the wound which is covered by a sealed dressing or bandage. The standard dressing does not use 'negative pressure'. The exact details of the materials used will be left to the discretion of the treating surgeon as per their routine practice but the details of each dressing applied in the trial will be recorded.

Negative-pressure wound therapy.
The NPWT dressing uses an 'open-cell', solid foam which is laid onto the wound followed by an adherent, sealed dressing. A hole is cut in the layer over the foam and a sealed tube is used to

connect the foam to a pump which creates a partial vacuum over the wound. The basic features of the NPWT are universal, but the exact details of the dressing will be left to the discretion of the treating surgeon. Again, the details of the dressings used will be recorded in the trial documentation.

Both groups of patients will then follow the normal post-operative management of patients with an open fracture of the lower limb. This will usually involve a 'second-look' operation after 48 hours, where a further debridement is performed and the wound closed (with sutures or a soft-tissue graft as necessary). Depending upon the specific injury and according to the treating surgeons' normal practice, the wound may be re-dressed again pending further surgery. Any further wound dressing will follow the allocated treatment until definitive closure/cover of the wound is achieved.

Intervention Type
Procedure/Surgery

Primary outcome measure
Disability Rating Index (DRI) - a self administered, 12-item Visual Analogue Scale questionnaire assessing the patients' own rating of their disability. This measure was chosen as it addresses 'gross body movements' rather than specific joints or body segments. Therefore, it will facilitate the assessment of patients with different fractures of the lower limb. This data will be collected at baseline, 3, 6, 9 and 12 months post-operatively.

Secondary outcome measures
1. Deep Infection; We will use the Centers for Disease Control and Prevention definition of a 'deep surgical site infection': that is a wound infection involving the tissues deep to the skin that occurs in the first year following the injury. We will use photographs of the wound at the 6-week clinical follow-up in order to provide an objective assessment of wound healing and infection. X-rays taken at 6 weeks and 12 months post-injury will be assessed for further indicators of infection - periosteal reaction/lysis at 6 weeks and chronic osteomyelitis at 12 months post-injury.
2. EQ-5D - a validated, generalised, quality of life questionnaire consisting of 5 domains related to daily activities with a 3-level answer possibility. The combination of answers leads to the QoL score.
3. Complications - all complications will be recorded
4. SF-36; The Short-Form 36 is a validated and widely-used health-related quality of life measure
5. Resource use will be monitored for the economic analysis. Unit cost data will be obtained from national databases such as the BNF and PSSRU Costs of Health and Social Care. Where these are not available the unit cost will be estimated in consultation with the UHCW finance department. The cost consequences following discharge, including NHS costs and patients' out-of-pocket expenses will be recorded via a short questionnaire which will be administered at 3, 6, 9 and 12 months post surgery. Patient self-reported information on service use has been shown to be accurate in terms of the intensity of use of different services.

Overall study start date
01/03/2012

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Aged 16 years or older
2. Present to the trial hospital within 72 hours of injury
3. Have an open fracture of the lower limb - graded as Gustilo and Anderson 2 or 3.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Minimum of 460

Key exclusion criteria
1. There are contra-indications to anaesthesia such that the patient is unable to have surgery
2. There is evidence that the patient would be unable to adhere to trial procedures or complete questionnaires, such as permanent cognitive impairment. It is expected that for a very small proportion of patients this exclusion criterion will only be determined after randomisation has taken place. These patients will then be excluded from the study and no patient identifiable data will be retained.

Date of first enrolment
01/03/2012

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Warwick
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

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Sponsor type
University/education

Website
http://www2.warwick.ac.uk/services/rss/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/09/2015		Yes	No
Results article	results	12/06/2018		Yes	No
Results article	qualitative study results	25/06/2018		Yes	No
Results article	results	01/12/2018		Yes	No
Results article	patient experience of recovery results	09/10/2019	23/10/2020	Yes	No