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Wound healing in surgical trauma

Submission date
07/12/2015

Recruitment status
No longer recruiting

Registration date
09/12/2015

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Major trauma is where a person has sustained serious and often multiple injuries. In many cases, it is the result of traffic accidents, falls and physical violence, and is one of the most common causes of death and long-term disability in people under the age of 45. Leg injuries are particularly common in cases of major trauma, and many patients require surgery to help fix broken bones. Many patients suffer from infection in surgical sites however in victims of major trauma this is thought to be as high as 40%. This is thought to be because the extensive damage to the muscles and other tissues can make patients' tissues less resistant to bacteria and more vulnerable to infection. Deep infection around the bone causes long-term problems for the patient, often required repeated operations and can even lead to amputation of the limb. Wound dressings are commonly used to prevent infections of surgical sites in adults; however the type of dressing used could reduce the risk of infection. New dressings are constantly being developed, however these are often introduced into the NHS without any formal testing in research projects. Negative pressure wound therapy (NPWT) is a technique which involves applying gentle suction to the surface of the wound as it heals. The aim of this study is to test the effectiveness of NPWT in comparison to standard dressings, at reducing rates of surgical site infections in major trauma patients.

Who can participate?
Major trauma patients aged 16 or over who need surgery to treat a broken leg.

What does the study involve?
Following surgery, participants are randomly allocated to one of two groups. For participants in the first group, the surgical wounds are dressed with a NPWT dressing. This consists of a foam pad, which is connected to a mini-pump to create a partial vacuum over the wound. For participants in the second group, their surgical wounds are dressed using an ordinary dressing which does not use negative pressure. 30 days after the injury occurred, the amount of participants who have had a deep infection is recorded. At the start of the study and again at 3 and 6 months, participants complete a number of questionnaires in order to measure their level of disability and quality of life, as well as how well their wound is healing. Their long-term disability and quality of life is also measured using a questionnaire at 1, 2, 3, 4 and 5 years.

What are the possible benefits and risks of participating?
There are no direct risks or benefits to participants taking part in the study.

Where is the study run from?
John Radcliffe Hospital, Oxford (lead centre) and 22 other hospitals

When is the study starting and how long is it expected to run for?
January 2016 to April 2023

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Juul Achten
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Study website
https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/whist

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number
192580

ClinicalTrials.gov number

Secondary identifying numbers
5.0; HTA 14/199/14, IRAS 192580

Study information

Scientific Title

A randomised controlled trial of standard wound management versus negative pressure wound therapy in the treatment of adult patients having surgical incisions for major trauma to the lower limb

Acronym
WHIST

Study objectives
The aim of this study is to compare the effectiveness of negative-pressure wound therapy with standard dressings for patients with major trauma requiring surgical incisions for the treatment of lower limb fractures.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1419914
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/161986/PRO-14-199-14.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Coventry and Warwickshire REC, 16/02/2016, ref: 16/WM/0006

Study design
Multi-centre randomized 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients with major trauma requiring surgery for a fracture to the lower limb.

Interventions
Patients with a fracture of the lower limb associated with major trauma usually have surgery on the next available trauma operating list. Some patients may be transferred to a Major Trauma Centre for definitive care – within the first 48 hours of injury – but will still have their initial surgery as soon as possible. All patients will receive a general or regional anesthetic. At the end of the initial operation, participants are randomly allocated to one of two groups.

Control Group: Participants receive standard of care wound dressing. The standard dressing for a surgical wound 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.

Intervention group: Participants receive a negative pressure wound therapy (NPWT) dressing. The NPWT dressing uses an 'open-cell', solid foam which is laid onto the wound as an intrinsic part of a sealed dressing. A sealed tube connects the dressing to a built in mini-pump which creates a partial vacuum over the wound.

In most cases the first dressing applied to the wound at the end of the operation is left in place until the wound is ready for the stitches etc to be removed – usually one to two weeks after the surgery. However, in some cases, depending upon the specific injury and according to the treating surgeons' normal practice, the wound may be re-dressed again on the ward. Any further wound dressing will be recorded and will follow the allocated treatment unless otherwise clinically indicated.

Intervention Type
Procedure/Surgery

Primary outcome measure
Deep infection rate in lower limbs is measured 30 days post-injury by the patient's treating clinical team using the Centre for Disease Control and Prevention definition of a deep surgical site infection.

Secondary outcome measures
Current secondary outcome measures (as of 18/12/2017):
1. Disability and quality of life are measured using the Disability Rating Index and the EQ-5D-5L at baseline (retrospective) and 3 and 6 months post-injury
2. Wound healing is measured using a validated patient reported questionnaire at 30 days, 3 and 6 months post-injury
3. Number and nature of further surgical interventions is assessed using patients medical records and patient self-report at 30 days, 3 and 6 months
4. Cost effectiveness is determined using national databases and patient resource questionnaires at 3 and 6 months post-injury
5. Long-term disability, chronic neuropathic pain and quality of life are determined using the Disability Rating Index (DRI), Neuropathic Pain 4 Questions (DN4) and EuroQol (EQ-5D-5L) respectively at 1, 2, 3, 4 and 5 years post-injury

Previous secondary outcome measures:
1. Disability and quality of life are measured using the Disability Rating Index and the EQ-5D-5L at baseline (retrospective) and 3 and 6 months post-injury
2. Wound healing is measured using a validated patient reported questionnaire at 30 days, 3 and 6 months post-injury
3. Number and nature of further surgical interventions is assessed using patients medical records and patient self-report at 30 days, 3 and 6 months
4. Cost effectiveness is determined using national databases and patient resource questionnaires at 3 and 6 months post-injury
5. Long-term disability and quality of life is determined using the Disability Rating Index at 1, 2, 3, 4 and 5 years post-injury

Overall study start date
01/01/2016

Completion date
30/04/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria (as of 18/12/2017):
1. Aged 16 years or older
2. Present to hospital within 72 hours of injury
3. Presence of major trauma (as defined by eligibility for the UK Trauma Audit Research Network (TARN) database)
4. Presence of a lower limb fracture requiring a surgical incision

Previous participant inclusion criteria:
1. Aged 16 years or older
2. Present to the trial hospital within 72 hours of injury
3. Presence of major trauma (as defined by eligibility for the UK Trauma Audit Research Network (TARN) database)
4. Presence of a limb fracture requiring a surgical incision

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
1540

Total final enrolment
1548

Key exclusion criteria
1. An open fracture of the lower limb which cannot be closed primarily
2. There is evidence that the patient would be unable to adhere to trial procedures or complete questionnaires

Date of first enrolment
07/07/2016

Date of final enrolment
17/04/2018

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
John Radcliffe Hospital
Headley Way
Oxford
United Kingdom
OX3 9DU

Study participating centre
University Hospital
University Hospitals Coventry and Warwickshire NHS trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Frenchay Hospital
North Bristol NHS trust
Frenchay Park Road
Bristol
United Kingdom
BS16 1JE

Study participating centre
North Tyneside General Hospital
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Queen's Medical Centre
Nottingham University Hospitals NHS trust
Derby Road
Nottingham
United Kingdom
NG7 2UG

Study participating centre
The James Cook University Hospital
Marton Road
Middlesborough
United Kingdom
TS4 3BW

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University Hospital Aintree
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
Hull Royal Infirmary
Hull and East Yorkshire Hospitals NHS Trust
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre

Kings College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Derriford Hospital
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Queen Elizabeth Hospital
University Hospitals Birmingham
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Study participating centre
Royal London Hospital
Whitechapel Road
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Brighton and Sussex University Hospitals
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Royal Stoke University Hospital
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle-upon-Tyne
United Kingdom
NE1 4LP

Study participating centre
St George's University of London
Cranmer Terrace
London
United Kingdom
SW17 0RE

Study participating centre
St Mary's Hospital
Praed Street
Paddington
London
United Kingdom
W2 1NY

Study participating centre
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Cardiff and Vale Orthopaedic Centre (CAVOC)
University Hospital Llandough
Penlan Road
Penarth
United Kingdom
CF64 2XX

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Joint Research Office
Churchill Hospital
Block 60
Oxford
England

United Kingdom
OX3 7LE

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the main phase of the study are likely to be presented at (inter)national conferences and in peer-reviewed journals in Summer 2019. The results of the long follow-up will be presented and published in the summer of 2023.

Intention to publish date
31/07/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/06/2018		Yes	No
Statistical Analysis Plan	statistical analysis plan	28/03/2019		No	No
Results article	results	11/02/2020	12/02/2020	Yes	No
Results article	results	01/08/2020	25/08/2020	Yes	No
HRA research summary			26/07/2023	No	No
Other publications	Cost analysis and pain medication use	15/06/2023	21/01/2025	Yes	No