

Wound healing in surgical trauma

Submission date 07/12/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/12/2015	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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

WHIST@ndorms.ox.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Juul Achten

Contact details

NDORMS

Kadoorie Centre- John Radcliffe Hospital

Oxford

United Kingdom

OX3 9DU

+44 (0)1865 223114

WHIST@ndorms.ox.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)

192580

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

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

United Kingdom

England

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

Marlon Road
Middlesbrough
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)

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

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?
Results article	results	11/02/2020	12/02/2020	Yes	No
Results article	results	01/08/2020	25/08/2020	Yes	No
Protocol article	protocol	07/06/2018		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
Statistical Analysis Plan	statistical analysis plan	28/03/2019		No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes