# Wound healing in surgical trauma

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
07/12/2015		[X] Protocol		
<b>Registration date</b> 09/12/2015	Overall study status Completed	[X] Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 21/01/2025	Condition category  Musculoskeletal Diseases	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

### Study website

https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/whist

# 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

**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