

# WHITE 7 - WHISH – Wound Healing in Surgery for Hip fractures

<b>Submission date</b> 31/05/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/05/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/07/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hip fractures affect 70 000 patients per year in the UK, and it is predicted that 100 000 people will suffer a hip fracture in the UK by 2020. Almost all patients undergo surgery to enable them to start walking again. However, between 2% and 7% of patients will get a wound infection. These infections are very serious and lead to a much longer hospital stay, more surgery and for half of the patients-death. In surgery, the use of negative pressure wound therapy (NPWT)-a type of suction dressing-is increasing rapidly. However it has not been tested rigorously in a formal trial, and it has not been looked at for hip fracture surgery specifically. The aim of this study is to better understand the rates of the infection problem in hip fracture surgery and to explore whether it will be feasible to run a large multicentre trial comparing NPWT with normal wound dressings.

### Who can participate?

Adults aged 65 years or older who have a hip fracture that requires surgery

### What does the study involve?

Participants who require surgery are randomly allocated to one of two groups. Both groups undergo the surgery. Those in the first group have the standard wound dressing applied after their wound is closed during surgery done to the standard level of care. Those in the second group receive a negative pressure wound therapy (NPWT) dressing. This uses solid foam laid on to the wound connected to a pump that creates a vacuum over the wound. Participants have their dressings on the wound until they need their stitches removed around one to two weeks after surgery. However, if they need to be re-dressed then this is recorded. Participants are assessed to see whether they develop an infection as well as the routine questions that are asked of all people who break their hip.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

University of Oxford (UK)

When is the study starting and how long is it expected to run for?  
March 2017 to August 2018

Who is funding the study?  
1. National Institute for Health Research (UK)  
2. Royal College of Surgeons of England (UK)

Who is the main contact?  
Mrs Lucy Sansom  
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**Study website**  
ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/white7

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Public

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

34527

## **Study information**

### **Scientific Title**

A randomised controlled feasibility trial of standard wound management versus negative pressure wound therapy in the treatment of adult patients having surgical incisions for hip fractures

### **Acronym**

WHISH

### **Study objectives**

Research Question:

To quantify the difference in the rate of deep infection after hip fracture surgery between patients using standard wound dressings and patients using Negative Pressure Wound Therapy (NPWT) dressings. This will in turn be used to define the sample size of a definitive multicentre randomised controlled trial.

Null hypotheses:

1. The rate of deep infection after 30 days, according to the CDC definition, will not be significantly different between the two patient groups
2. There will be no difference in mortality rate between the two patient groups
3. The number and nature of further surgical interventions related to the injury will not be significantly different between the two patient groups
4. There will be no difference in the distribution of patient-reported functional outcome and quality of life measures between the patient groups

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Oxford C Research Ethics Committee, 28/04/2017, 17/SC/0207

### **Study design**

Randomised; Interventional; Design type: Treatment, Device, Surgery

### **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 below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Specialty: Injuries and emergencies, Primary sub-specialty: Injuries and emergencies; UKCRC code/ Disease: Injuries and Accidents/ Injuries to the hip and thigh, Infection/ Other infectious diseases

**Interventions**

Patients with a fracture of the hip will present at the trial centres to undergo surgery on the next planned trauma operating list. At the end of their surgery they will be randomised to one of two groups via the use of a centralised computer randomisation service RRAMP (<https://rramp.octru.ox.ac.uk>) provided by the Oxford Clinical Trials Research Unit (OCTRU). Randomisation will be stratified by centre to ensure the participants from each study site have an equal chance of receiving each intervention.

Group 1: Participants have the standard wound dressing applied after closure of the wound during surgery as per local hospital procedures.

Group 2: 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 to be removed which is 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.

Participants are assessed to see whether they develop an infection as well as the routine questions that are asked of all people who break their hip.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Deep Infection, using the Center 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 within 30 days post surgery

**Secondary outcome measures**

1. Rate of Mortality
2. Health-related quality of life is measured using the EuroQol EQ-5D-5L questionnaire at baseline and 4 months post-surgery
3. Complications and surgical interventions related to the index wound are measured using questionnaires at 4 months
4. Cost consequences and resource use (NHS costs, patient's out-of-pocket expenses) are measured using a short questionnaire at four months post injury
5. Mobility is measured using questionnaires at the baseline and 4 month CRF
6. Residential status is measured using questionnaire at baseline and at 4 months
7. Recruitment rate is measured using questionnaire at baseline
8. Retention rate is measured using screening logs at baseline

The core outcome set available via [<http://www.comet-initiative.org/studies/details/274>] has been consulted in the construction of the study outcome measures

**Overall study start date**

01/03/2017

**Completion date**

17/08/2018

## Eligibility

**Key inclusion criteria**

1. Patients aged 65 years or older
2. Patients that have a hip fracture requiring surgical treatment

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Planned Sample Size: 464; UK Sample Size: 464

**Key exclusion criteria**

Patients having percutaneous screw fixation of an undisplaced intracapsular fracture of the hip.

**Date of first enrolment**

15/06/2017

**Date of final enrolment**

22/02/2018

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre****University of Oxford**

Clinical Trials Research and Governance

Joint Research Office

Churchill Hospital

Block 60

Oxford

United Kingdom

OX3 7LE

**Study participating centre****Poole Hospital**

Poole Longfleet Road

Poole

United Kingdom

BH15 2JB

**Study participating centre****Norfolk & Norwich University Hospital**

Colney Lane

Norwich

United Kingdom

NR4 7UY

**Study participating centre****Nottingham Hospital**

Hucknall Road

Nottingham

United Kingdom

NG5 1PB

**Study participating centre****Southmead Hospital**

Southmead Road

Westbury-on-Trym

Bristol

United Kingdom  
BS10 5NB

## Sponsor information

### Organisation

University of Oxford

### Sponsor details

Clinical Trials Research and Governance  
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

**Funder Name**

Royal College of Surgeons of England

**Alternative Name(s)**

RCS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**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.

**Intention to publish date**

31/12/2019

**Individual participant data (IPD) sharing plan**

The current data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	12/04/2018	26/11/2020	Yes	No
<a href="#">Results article</a>		01/04/2021	29/07/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No