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

Submission date
31/05/2017

Recruitment status
No longer recruiting

Registration date
31/05/2017

Overall study status
Completed

Last Edited
29/07/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

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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 diiference 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
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
University of Oxford

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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?
Protocol article	protocol	12/04/2018	26/11/2020	Yes	No
Results article		01/04/2021	29/07/2022	Yes	No
HRA research summary			28/06/2023	No	No