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WHITE 14-PRESSURE 3: An investigation of people 60 years and over with a broken hip to determine whether using specialised heel pressure equipment can lower the number of people developing a pressure ulcer on the heel after surgery

Submission date
15/06/2023

Recruitment status
No longer recruiting

Registration date
29/06/2023

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Every year around 70,000 people in the UK break their hip. Hip fractures can take a long time to recover from and can lead to a range of complications associated with reduced mobility, including pressure ulcers. Pressure ulcers (PU) are caused by sitting/lying in one position or being unable to move a part of the body. They cause pain, discomfort, and distress to patients, leading to reduced quality of life and sometimes death. They range in seriousness: Category 1 is a reddened area; Category 2 is a blister/skin loss, and Category 3 and 4 are deep wounds. People with a hip fracture are at high risk of heel PU development due to difficulty moving their affected leg and the use of the opposite heel when pushing themselves up/moving in bed. Factors which lead to hip fractures are also risks for PU development, for example, frailty. If PUs develop on the heel of a person with a hip fracture, they cause added problems as they take a long time to heal (often months) reducing mobility, affecting the shoes they can wear and increasing their time to start walking again. This project is about the prevention of heel PUs in patients with hip fractures. Usual care for PU prevention includes specialist mattresses, electric-powered bedframes and repositioning in bed.

Who can participate?
Patients aged 60 years and over who will have surgery to treat a broken hip. People cannot take part if they already have a pressure ulcer or have a pressure ulcer prevention device already in use.

What does the study involve?
PRESSURE 3 will compare usual care alone with usual care plus one of two types of specialist heel equipment:

1. Heel off-loading devices ensuring no contact with the heel. They include foam troughs and boots which are applied to the legs
2. Constant low-pressure (CLP) devices which are softer than a mattress and so reduce the pressure at the heel. They include pads made of foam or gel and are laid on top of the bedsheet. Both types of specialist equipment are currently used as a standard for specific patient groups in the NHS but are not routinely used for patients with hip fractures.

We will study 3102 patients with hip fractures from at least 30 NHS hospitals. Participants will have a 1 in 3 chance of getting the off-loading device, the low-pressure device or usual care as decided by a computer. To make the study results relevant to all NHS patients with hip fractures we will include both patients who can provide consent to take part themselves as well as patients who may be confused or have dementia by asking for agreement from their next of kin or a consultee (someone who is acting in the best interest of the patient, either a healthcare professional or someone who has a close personal relationship with the patient).

Patients who agree to take part in this research will have their heels assessed for pressure ulcers twice weekly until they leave the hospital. The study will compare the number of participants who develop a heel pressure ulcer. At 4 months, we will ask the participants to complete a simple questionnaire by telephone, email, or post to tell us about their recovery after leaving the hospital.

What are the possible benefits and risks of participating?
People who take part in the study might get a device which potentially can prevent them from developing a heel pressure ulcer. The risks of taking part have been deemed low – there is a small chance of the development of pressure ulcers on other parts of the body or skin reactions to the devices.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
August 2022 to July 2025

Who is funding the study?
National Institute of Health and Care Research (NIHR) (UK). The grant provided falls under the Health Technology Assessment scheme.

Who is the main contact?
Central trial team, white14-pressure3@ndorms.ox.ac.uk

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2020-003719-83

Integrated Research Application System (IRAS)
287755

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 56739, IRAS 287755

Study information

Scientific Title
World Hip Trauma Evaluation Appendix 14 - Pressure Ulcer Prevention 3: A randomised clinical trial assessing early heel-specific adjunct devices for heel pressure ulcer prevention in people with a fractured hip (PRESSURE 3)

Acronym
WHiTE14-PRESSURE 3

Study objectives
To establish if the incidence of new Category ≥2 heel pressure ulcers (PUs) from diagnosis of a hip fracture to index hospital discharge or 30 days whichever is soonest is different between Standard Care plus early initiation of a Heel Off-loading Device, Standard Care plus early initiation of a Constant Low-Pressure (CLP) Device and Standard Care alone in patients aged 60 and over with a hip fracture which in the opinion of the treating clinical team may benefit from surgical treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/01/2021, South Central – Berkshire Research Ethics Committee (Easthampstead Baptist Church, Southill Road, Bracknell, RG12 7NS, United Kingdom; +44 (0)2071048138; berkshire.rec@hra.nhs.uk), ref: 20/SC/0452

Study design
Randomized interventional prevention management-of-care study

Primary study design

Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Prevention of heel pressure ulcer after surgery for a broken hip

Interventions
WHiTE 14-PRESSURE 3 is a randomised comparison appended to the World Hip Trauma Evaluation (WHiTE) Platform. WHiTE is a platform trial designed to efficiently deliver multiple randomised comparisons of interventions for patients aged 60 years and over with a hip fracture. The platform and its appended randomised comparisons are governed by one single set of ethical and regulatory approvals and an explicit legal basis and processing purpose for the use of patient-level data. The Platform affords a common core dataset and documentation.

Individual randomised comparisons are not dependent on each other and each will have unique start and stop dates and publication of results without compromising the integrity of the platform.

Specifically for WHiTE 14-PRESSURE 3: randomisation will be on a 1:1:1 basis stratified by recruitment centre, consent type (individual versus consultee), and skin status at randomisation (Skin Status '(0 or A versus Category 1 PU or suspected deep tissue injury)') using a minimisation algorithm (including a small number to seed the algorithm and a random element) ensuring allocation concealment to the point of randomisation to:
* Standard Care plus Constant Low-Pressure Devices for up to 30 days or index hospital discharge (whichever is sooner). Constant Low-Pressure devices distribute pressure over a larger surface area and reduce the magnitude of the applied pressure by increasing the overall contact area
*Standard Care plus Heel Off-loading Devices for up to 30 days or index hospital discharge (whichever is sooner). Off-loading devices completely eliminate heel pressure
*Standard Care: In this pragmatic randomised comparison, any interventions prescribed for the prevention of PUs to participants in the standard care group will be at the discretion of the attending clinical team. Records will be made of the type of mattress and additional heel adjuvant devices each participant has been assigned pre-randomisation.

Intervention Type
Other

Primary outcome(s)
Skin status assessments of the heels will be undertaken using the international classification scale (EPUAP/NPIAP/PPPIA) by a trained member of the local research team at pre-randomisation and twice weekly up to discharge or 30 days whichever is sooner.

This assessment will be used to compare the incidence of new Category ≥2 heel PUs from diagnosis of a hip fracture to index hospital discharge or 30 days whichever is soonest between the treatment groups

Key secondary outcome(s))
Skin status assessment as described for the primary outcome measure will also be used to:
1. Compare the incidence of new Category 1 heel PUs from diagnosis of a hip fracture to index

hospital discharge or 30 days whichever is soonest between treatment groups in participants with normal or Category A skin status on the heel(s) at randomisation
2. Compare the overall incidence of new Category ≥1 heel PUs from diagnosis of a hip fracture to index hospital discharge or 30 days whichever is soonest between treatment groups in participants with normal or Category A skin status on the heel(s) at randomisation
3. Compare the progression of Category ≥1 heel PUs to a higher Category from diagnosis of a hip fracture to index hospital discharge or 30 days whichever is soonest between treatment groups

Other secondary outcome measures include:
4. The proportion of resolved heel PUs at 4 months post-diagnosis of a hip fracture between treatment groups in participants with a Category ≥1 heel PU at their final pre-discharge/30-day in-hospital skin status measured using a bespoke patient-reported questionnaire on wound status
5. Subjective mobility status measured using the modified New Mobility Score at 4 months post-diagnosis of a hip fracture
6. Residential status measured using the UK National Hip Fracture Database Residential Status at 4 months post-diagnosis of a hip fracture
7. Mortality risk measured using death notification up to 4 months post-diagnosis of a hip fracture
8. Risk and pattern of complications measured using a bespoke complications questionnaire and routinely collected hospital data up to 4 months post-diagnosis of a hip fracture
9. Resource use from an NHS and personal social services perspective calculated using a bespoke resource use questionnaire up to 4 months post-diagnosis of a hip fracture
10. Comparative cost-effectiveness of the trial treatments using resource-use questionnaires and EQ-5D-5L up to 4 months post-diagnosis of a hip fracture

Completion date
31/07/2025

Eligibility

Key inclusion criteria
Platform inclusion criteria:
Aged 60 years old and over presenting to a WHiTE recruitment centre for treatment of a hip fracture

Additional inclusion criteria for PRESSURE 3:
1. Diagnosis of hip fracture within 48 hours of randomisation
2. In the opinion of the treating clinical team, the patient may benefit from surgical treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Sex
All

Key exclusion criteria
Platform exclusion criteria:
1. Previous participation in the same randomised comparison
2. A second hip fracture (on the other side), while the patient is still enrolled in the Platform following their first hip fracture,
Additional exclusion criteria for PRESSURE 3:
3. A heel off-loading or CLP device has been assigned prior to randomisation
4. There is an existing Category 2-4 or Unstageable PU on either heel or ’not applicable' on both heels (ie no evaluable heel sites)
5. There is a contra-indication to the interventions e.g. allergy to device material

Date of first enrolment
10/07/2023

Date of final enrolment
30/05/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

Government

Funder Name
National Institute for Health and Care 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
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Matthew Costa, matthew.costa@ndorms.ox.ac.uk. Requests can be made 2 years after the publication of the trial results. The decision on the level of access granted and the purpose for which it might be made available will be guided by the Oxford Clinical Trials Research Unit and the University of Oxford policies regarding data sharing that are in place at the time of the request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes