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Evaluating whether surgical reconstruction is better than non-surgical treatment for people admitted to hospital who have a severe pressure ulcer

Submission date
13/01/2020

Recruitment status
No longer recruiting

Registration date
14/01/2020

Overall study status
Completed

Last Edited
03/07/2024

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Being immobile for too long can lead to discomfort, for example pins and needles or pain. These sensations prompt us to move and this avoids poor blood flow which can lead to pressure ulcers (sometimes called bed sores). Pressure ulcers mainly affect older people confined to a bed or chair. However, younger or seriously ill patients with limited movement, for example due to a spinal injury, can be affected.

Pressure ulcers are a serious problem for patients and their carers. They range in severity from red skin (Stage 1) to deep wounds through muscle to bone (Stage 4). Pressure ulcers have a major impact on quality of life; they may heal slowly and become infected, and can increase the risk of dying in older people. They are also a costly problem for the National Health Service (NHS). People with pressure ulcers are usually treated in the community but may need hospital care. Common treatments for pressure ulcers include pressure relief, dressings and encouraging movement and change of position. Surgery can be used to try and close deep pressure ulcers but in the United Kingdom (UK) this treatment is not common. Finding out whether surgery works as a treatment is very important to people affected by pressure ulcers. At the moment, it is not clear which patients with pressure ulcers may benefit from an operation and which of the different ways of doing the surgery seems best.

Who can participate?
Records from patients described in Hospital Episode Statistics with index admission (admitted patient care dataset) with a severe pressure ulcer between April 2012 and March 2019.

What does the study involve?
The SIPS study will analyse data collected routinely in the NHS over the last 7 years. The study will describe the care that has been provided in England to patients with severe pressure ulcers, the kinds of patients who have been treated in different ways and examine how care is different in different places. To inform whether surgical treatments should be more widely available, the

study will identify patients who were similar when admitted to hospital with a severe pressure ulcer and compare health outcomes (such as going back to hospital and death) among those who did and did not have surgery.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Bristol Trials Centre (BHI Hub), UK

When is the study starting and how long is it expected to run for?
April 2020 to June 2023

Who is funding the study?
National Institute for Health Research (HTA programme), UK

Who is the main contact?
Prof. Barnaby Reeves
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Study website
https://bristoltrialscentre.blogs.bristol.ac.uk/details-of-studies/sips/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
v1.0

Study information

Scientific Title
Health outcomes in matched groups of patients admitted to hospital who have a severe pressure ulcer who do or do not have a surgical reconstruction operation.

Acronym
SIPS

Study objectives
Surgical reconstruction improves long term health outcomes in people who have a severe pressure ulcer during a hospital admission

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics approval required. Secondary analysis of routinely collected data (UK hospital episode statistics)

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Severe pressure ulcers

Interventions

Current intervention as of 16/12/2020:
Reconstructive surgery operations coded with OPCS-4 codes: S17, S18, S19, S20, S21, S22, S23, S24, S25, S26 and S27. Surgical debridement (OPCS code S57.1) will also be described.

Participants will have been treated in hospital for a severe pressure ulcer (potentially among other diagnoses). Our intention is to capture all diagnoses at 'enrolment' (to characterise participants at the time of the index hospital admission) and then describe all procedures administered in that admission and subsequently, and describe outcomes such as duration of index admission, and time to readmission with a pressure ulcer related diagnosis.

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Previous intervention:
Reconstructive surgery operations coded with OPCS-4 codes: S17, S18, S19, S20, S21, S22, S23, S24, 25, S26. Surgical debridement (OPCS code S57.1) will also be described.

Participants will have been treated in hospital for a severe pressure ulcer (potentially among other diagnoses). Our intention is to capture all diagnoses at 'enrolment' (to characterise participants at the time of the index hospital admission) and then describe all procedures administered in that admission and subsequently, and describe outcomes such as duration of index admission, and time to readmission with a pressure ulcer related diagnosis.

Intervention Type
Procedure/Surgery

Primary outcome measure
Time to first subsequent admission with a pressure-ulcer related diagnosis measured using patient records

Secondary outcome measures
Measured using patient records:
1. Type of surgical reconstruction (OPCS code), if any
2. Duration of index admission
3. Time to first subsequent admission with a pressure-ulcer related diagnosis
4. Rate of subsequent admissions with a pressure-ulcer related diagnosis
5. Surgical reconstruction after discharge for the index admission
6. Mortality

Overall study start date
01/09/2018

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 16/12/2020:
Patients described in Hospital Episode Statistics with index admission (admitted patient care dataset) with a severe pressure ulcer (ICD-10 codes L89.2, L89.3, L89.9) or any pressure ulcer (L89.X) during a period of 8 years (01/04/2011-31/03/2019), linked with other HES APC and

outpatient episodes and mortality data (to 31/03/2019). The target population for the HES cohort is: patients aged >=18 years in England admitted to hospital, with an ICD-10 diagnosis code for a severe pressure ulcer.

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Previous participant inclusion criteria:
Patients described in Hospital Episode Statistics with index admission (admitted patient care dataset) with a severe pressure ulcer (ICD-10 codes L89.2, L89.3, L89.9) during a period of 7 years (01/04/2012-31/03/2019).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
All patients with a record as described will be eligible (estimated 35,000 per year)

Total final enrolment
291326

Key exclusion criteria
There are no secondary outcome measures

Date of first enrolment
01/04/2011

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Trials Centre (BHI Hub)
Bristol Medical School
Bristol Royal Infirmary
Bristol

United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

Sponsor details
Education & Research Centre, Level 3
Upper Maudlin Street
Bristol, BS2 8AE
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England
United Kingdom
BS2 8AE
+44 (0)117 342 0233
research@uhbristol.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/

ROR
https://ror.org/04nm1cv11

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
Some co-applicants are contributing to NHS England's National Wound Care Strategy, which will provide a key avenue to communicate findings. We will report findings at conferences and in high-impact general journals. We will impact on clinical practice by engaging with professional bodies; study collaborators have strong links with organisations including the Tissue Viability Society and NICE.

We will ensure members of our Patient and Public Involvement (PPI) forum are actively involved in carrying out activities relating to dissemination and public engagement. Opportunities such as talks to local groups and other events will be considered on a case by case basis. A lay summary of the research and its findings will be written and added to collaborator University websites and relevant blogs. To maximise visibility and accessibility of the material, we will use Google metrics to ensure our wording on the relevant site means the web page is located high in the returned list from a Google search. We also have close links with local Trusts and will aim to distribute the summary locally at relevant patient events in addition to online content.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to restrictions imposed by the data source.

To support further engagement work we will liaise with experienced colleagues at the NIHR Manchester Biomedical Research Centre and Public Programmes at Manchester University NHS Foundation Trust to undertake a range of engagement activities at public events including the Manchester Science Festival. These activities will raise the profile of pressure ulcers and research to improve their management.

We will link with existing networks at the University of Manchester to ensure our findings are presented locally to both academics, clinicians and members of the public, for example the Manchester Institute for Collaborative Research on Ageing, seminars for which are regularly well-attended by each of these groups.

We will publish relevant journal articles and attend at least one key conference. We will also draft media-friendly articles for relevant trade journals such as the Nursing Times and Nursing Standard. We will summarise the work using widely accessed, research-focused resources such as The Conversation and Kudos. We will also contact the NIHR Dissemination Centre to ask for advice where there are specific findings we want to publicise. Publications will be supported by targeted social media activity, especially through Twitter, using current accounts that link to a wide range of relevant stakeholder groups to ensure wide dissemination alongside a study specific account. Where required, press releases and media support will be provided.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	04/11/2020	17/08/2022	No	No