ISRCTN13661431 https://doi.org/10.1186/ISRCTN13661431

INITIATE: Increased mobility in hospital after hip fracture

Submission date
16/07/2024

Recruitment status
Recruiting

Registration date
22/07/2024

Overall study status
Ongoing

Last Edited
06/06/2025

Condition category
Musculoskeletal Diseases

[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
Each year there are 70,000 new hip fractures in the UK, with an ongoing annual cost to health and social care services of £3 billion. After this injury, mobility and independence are so badly affected that one in six people never return home. This downward spiral of immobility and dependence contributes to a quarter of people dying within one year of the injury. National mobility targets have been set for hospitals. Firstly patients should be helped out of bed within 48 hours of receiving surgery and secondly, they should receive two hours of rehabilitation per week. Patients whose care exceeds these targets seem to recover more quickly than other patients. Consequently, patients and their carers have asked if increasing ward-based mobilising would allow people to get back home more quickly and to continue living independently. This study wants to find out if more ward-based mobilisation activity after hip fracture surgery allows people to get home quicker and allows them to stay living in their own homes longer.

Who can participate?
Adults aged ≥ 60 years having surgery for a fracture of the hip

What does the study involve?
Study participants will provide additional data to the research team at baseline (during their hospital stay), and then around 30 days and 120 days after their surgery.

What are the possible benefits and risks of participating?
There is no specific advantage to taking part in this study. However, the study results will help to improve the care of patients with a broken hip in the future.

Where is the study run from?
The study is run by the Oxford Trauma and Emergency Care research group, which is part of the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences of the University of Oxford.

When is the study starting and how long is it expected to run for?
April 2024 to November 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) through its Health Technology Assessment (HTA) programme

Who is the main contact?
1. Prof Matt Costa, matthew.costa@ndorms.ox.ac.uk
2. Prof Rebecca Kearney, becky.kearney@bristol.ac.uk

Study website
https://initiate.octru.ox.ac.uk/

Contact information

Type(s)
Public, Scientific

Contact name
Dr Gratian Vandici

Contact details
INITIATE Trial Manager, Kadoorie Centre, Level 3, John Radcliffe Hospital, Headley Way
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 227226
initiate@ndorms.ox.ac.uk

Type(s)
Principal Investigator

Contact name
Prof Matt Costa

ORCID ID
https://orcid.org/0000-0003-3644-1388

Contact details
Chief Investigator, Kadoorie Centre, Level 3, John Radcliffe Hospital, Headley Way
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 223114
matthew.costa@ndorms.ox.ac.uk

Type(s)
Principal Investigator

Contact name
Prof Rebecca Kearney

ORCID ID
https://orcid.org/0000-0002-8010-164X

Contact details
Co-Lead Investigator, Bristol Trials Centre, Bristol Medical School, 1–5 Whiteladies Road, Clifton
Bristol
United Kingdom
BS8 1NU
+44 (0)117 4551727
becky.kearney@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
336892

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR150983, CPMS 62672, IRAS 336892

Study information

Scientific Title
INITIATE: Increased mobility in hospital after hip fracture

Acronym
WHiTE 15: INITIATE

Study objectives
To determine whether a usual care rehabilitation strategy or usual care with an additional mobility-focused intervention is superior for patients aged ≥ 60 years, after hip fracture surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/07/2024, Yorkshire & The Humber - Leeds East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8171, (0) 2071048137, (0)207 104 8357; leedseast.rec@hra.nhs.uk), ref: 24/YH/0113

Study design
Multi-centre two-arm unblinded cluster randomized controlled trial with embedded process and economic evaluations

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital, Medical and other records, Telephone

Study type(s)
Treatment

Participant information sheet
Patient information material can be found at https://initiate.octru.ox.ac.uk/

Health condition(s) or problem(s) studied
Mobility in hospital after hip fracture

Interventions
INITIATE is a multi-centre, two-arm, unblinded, cluster randomised controlled trial (RCT) with embedded process and economic evaluations.
The study will recruit 2310 patients (1155 in each of 2 groups) who have received surgery for a fracture of the hip, from approximately 22 NHS hospitals in the UK.
Recruitment centres will be cluster randomised to either Intervention or Control. Recruitment centres will be allocated in a 1:1 ratio using a computer-generated randomisation minimisation sequence.
Intervention: Usual care with additional ward-based mobilisation activities.
Control: Usual care.
Participants will provide data to the research team about their injury and recovery at baseline (during their hospital stay), and then around 30 days and 120 days after their surgery.
Follow-up contacts at 30 and 120 days post-surgery will be completed with the participant or a proxy either via telephone interviews by a member of the central research team, or through electronic means.
A process evaluation will take place to determine to what extent the cluster RCT protocol is operationalised within the orthopaedic trauma units and determine the extent to which the INITIATE intervention has been delivered per protocol (fidelity) and implemented (adherence). The process evaluation will take place in all intervention sites.

Intervention Type
Behavioural

Primary outcome measure
DAH30 (days alive and at home up to 30 days post-hip fracture surgery) will be measured using participant questionnaires and medical records at 30 days

Secondary outcome measures
1. DAH120 (days alive and at home up to 120 days post-hip fracture surgery) will be measured using participant questionnaires and medical records at 120 days
2. Health-related quality of life will be measured using EQ-5D-5L pre-injury, at 30 days, and 120 days
3. Mobility will be measured using mNMS (modified New Mobility Score) pre-injury and at 30 days
4. Basic mobility at discharge will be measured using CAS (Cumulated Ambulation Score) at

discharge
5. Residential status, mortality, rate of complications, rate of falls resulting in fracture or head injury, and resource use will be using participant questionnaires and medical records at 30 days and 120 days
6. The extent to which the cluster RCT protocol is operationalised within the orthopaedic trauma units and the extent to which the INITIATE intervention is adopted and embedded will be measured through intervention analysis and intervention adherence, based on a thematic analysis of interviews with participants (and relative/friend/informal carer as required) and interviews and focus groups with recruitment centre staff during the embedded process and economic evaluations part of the study

Overall study start date
01/04/2024

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Aged 60 years and over
2. With and without capacity
3. Presenting to a WHITE recruitment centre for treatment of a hip fracture or who has received surgery for a hip fracture in the past 48 hours

Participant type(s)
Patient

Age group
Mixed

Lower age limit
60 Years

Sex
Both

Target number of participants
Planned Sample Size: 2310; UK Sample Size: 2310

Key exclusion criteria
A patient will not be eligible for the study if ANY of the following apply:
1. A fracture caused by an area of abnormal bone (e.g., a tumour)
2. A pre-existing contraindication to mobilising after surgery
3. A patient who had severely limited mobility prior to injury (i.e confined to bed, transfer from bed to chair only)
4. Previous participation in INITIATE or actively engaged in other hip fracture research with contralateral hip fracture

Date of first enrolment

01/08/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Stepping Hill Hospital
Stockport NHS Foundation Trust
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Road
Walsgrave
Coventry
United Kingdom
CV2 2DX

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre

Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Study participating centre
University Hospital of North Durham
University Hospital of Durham
Dryburn Hospital
North Road
Durham
United Kingdom
DH1 5TW

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5ST

Study participating centre
Queens Medical Centre, Nottingham University Hospital
Derby Road

Nottingham
United Kingdom
NG7 2UH

Study participating centre
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Royal Preston Hospital
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
George Eliot Hospital
Lewes House
College Street
Nuneaton
United Kingdom
CV10 7DJ

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Governance, Ethics & Assurance, Joint Research Office, 1st floor, Boundary Brook House, Churchill Drive, Headington
Oxford
England
United Kingdom
OX3 7GB
None provided
rgea.sponsor@admin.ox.ac.uk

Sponsor type
Hospital/treatment centre

Website
https://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Any requests for data sharing will be submitted to Prof Matt Costa (matthew.costa@ndorms.ox.ac.uk) and Prof Becky Kearney (becky.kearney@bristol.ac.uk) and decided on a case-by-case basis. No data will be released for sharing until after the trial has closed to recruitment and been analysed.

IPD sharing plan summary
Available on request