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A study to improve the care pathways for people, 60 years and over, in South Asia with a broken hip

Submission date
12/06/2024

Recruitment status
Recruiting

Registration date
11/07/2024

Overall study status
Ongoing

Last Edited
18/12/2024

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
A broken hip (hip fracture) is a serious injury that requires surgery to repair or replace the broken bone followed by a long period in hospital to recover. Older adults are more likely to break their hip as their bones are weakened by a health condition known as osteoporosis. Around a quarter of patients with hip fractures die within a year and those that survive have a permanent loss of quality of life. Looking after older, often frail, patients following a hip fracture requires healthcare professionals from many different backgrounds. These include surgeons, doctors specialising in looking after older patients, nurses and therapists. In the UK, a collaborative approach between all healthcare professionals in taking care of these patients has reduced the number of people dying after hip fracture and improved their quality of life. It has also reduced healthcare costs. Asia is particularly affected by rapidly ageing populations. The number of people experiencing hip fractures is expected to increase from 1.1 million now to 2.6 million in 2050. This study is about testing the benefits of such 'multi-disciplinary' care in low- and middle-income countries (LMIC) in Asia. The HIPCARE study will test a multi-disciplinary care approach in five LMICs: India, Nepal, Philippines, Thailand, and Vietnam. It will focus on three key markers of good quality care for patients with a hip fracture: 1. Reducing delays to surgery, 2. Reducing the time taken for patients to start walking after surgery and 3. speeding up general medical assessment. The study will see if hospitals that have training and support to help with multi-disciplinary care can improve patient's quality of life compared with hospitals that continue with their usual patient care pathways.

Who can participate?
Patients at participating hospitals aged 60 years and over who are having surgery for a hip fracture

What does the study involve?
Hospitals that take part will randomly allocate participants to continue with their usual care pathways or be given additional training and support with multi-disciplinary care. Patients who consent to will receive the standard care in their hospital. They will answer a set of questions about daily life before their injury. Information about the treatment and care they receive in

hospital will be taken from their medical notes. After 4 months, participants will be contacted and asked a set of questions about their daily lives, as well as some additional questions about their care and treatment expenses. Some participants may be invited to talk to a researcher with other participants in a focus group, in more detail about their injury and taking part in the study.

What are the potential benefits and risks of participating?
There are no specific risks or benefits to taking part in the study as participants will be following the treatment and care plan of their hospital. By helping us to have a better understanding of treatment and recovery after hip fracture, the service may be improved for other patients in the future.

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

When is the study starting and how long is it expected to run for?
November 2022 to October 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR), Research on Interventions for Global Health Transformation

Who is the main contact?
UK central trial team: hipcare@ndorms.ox.ac.uk

Study website
https://hipcare.ndorms.ox.ac.uk/

Contact information

Type(s)
Principal Investigator

Contact name
Prof Matthew Costa

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR203194

Study information

Scientific Title
A cluster randomised controlled trial with embedded process evaluation to investigate the clinical and cost effectiveness of multidisciplinary care in the management of patients with a fracture of the hip

Acronym
HIPCARE

Study objectives
To determine if quality of life for patients in low- and middle-income Countries in Asia after hip fracture can be improved with the introduction of multi-disciplinary care training and support, and whether it reduces healthcare costs, compared with usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/07/2023, Oxford Tropical Research Ethics Committee (Research Services, Research Governance, Ethics & Assurance Boundary Brook House, Churchill Drive, Oxford, OX3 7GB, United Kingdom; +44 (0)1865 282106; oxtrec@admin.ox.ac.uk), ref: 520-23

Study design
Multicentre interventional cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Hip fracture

Interventions
Hospitals will be randomised to the HIPCARE intervention or usual care, via a centralised computer-based process stratified by country and will be carried out in advance of the start of recruitment.

Intervention arm:
The hospitals allocated to the HIPCARE intervention will be given additional funds to allocate the time of a senior clinician to act as an Intervention Champion. The local Principal Investigator and the Intervention Champion will establish a multi-disciplinary HIPCARE Working Group. HIPCARE intervention hospitals will be provided with a multi-disciplinary training package with online support. This will be focussed on: 1. Reducing delays to surgery, 2. Reducing the time taken for patients to start walking after surgery and 3. speeding up general medical assessment.

Control arm:
Patients will be treated as per the pre-trial pathways for hip fracture patients.

Intervention Type
Mixed

Primary outcome measure
Health-related quality of life measured using EuroQol-5D–5L at baseline and 120 days post-surgery

Secondary outcome measures
1. Mortality, measured using death notification data up to 120 days post-surgery
2. Mobility, measured using the Modified New Mobility Score (mNMS) at baseline and 120 days post-surgery
3. Residential status measured using a bespoke questionnaire at baseline and 120 days post-surgery
4. Complication rate measured using medical records and a bespoke questionnaire at 120 days post-surgery

5. Healthcare and broader resource implications measured using medical records and bespoke questionnaire at baseline and 120 days post-surgery
6. Estimated cost-effectiveness of the trial treatments measured using medical records, bespoke questionnaire, and the Euroqol-5D-5L at 120 days post-surgery

Overall study start date
01/11/2022

Completion date
31/10/2026

Eligibility

Key inclusion criteria
Patients aged 60 years or over having surgery for a hip fracture.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
60 Years

Sex
Both

Target number of participants
9000

Key exclusion criteria
The participant or a carer cannot complete follow-up at 120 days

Date of first enrolment
06/11/2024

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
India

Nepal

Philippines

Thailand

Viet Nam

Study participating centre
University of the Philippines Manila
8/F RCB
Philippine General Hospital
Taft Avenue
Ermita
Manila
Philippines
N/A

Study participating centre
Mahidol University, Faculty of Medicine Ramathibodi Hospital
999 Phuttamonthon 4 Rd
Salaya
Nakhon Pathom 73170
Thailand
N/A

Study participating centre
Kathmandu Medical College Public Limited
Baburam Acharya Sadak 184
Sinamangal
Kathmandu
Nepal
N/A

Study participating centre
The Hanoi University of Public Health
1A Duc Thang
North Tu Liem
Ha Noi
Viet Nam
N/A

Sponsor information

Organisation

University of Oxford

Sponsor details
Research Governance, Ethics and Assurance Team (RGEA)
Research services, University of Oxford, Joint Research Office
Boundary Brook House, Churchill Drive,
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Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Research on Interventions for Global Health Transformation (RIGHT) programme

Results and Publications

Publication and dissemination plan
The protocol will be published before recruitment has been completed. The statistical analysis plan will be published before the final data has been collected. Main clinical results and health economic evaluation will be published in high-impact peer-reviewed journals after completion of the initial follow-up period.

Intention to publish date
01/10/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Lead Investigator (Prof Matt Costa, hipcare@ndorms.ox.ac.uk). Each

request will be reviewed and decided upon on a case-by-case basis. Participants will be informed via the Participant Information Sheet (and will consent to the contents of this PIS) of the possibility of de-identified datasets being made available following appropriate requests.

IPD sharing plan summary

Available on request