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WHiTE16-DELPHIC: An investigation of people 60 years and over with a broken hip to determine whether they are less likely to have delirium after hip surgery if we treat them with corticosteroids during the operation

Submission date
08/12/2025

Recruitment status
Recruiting

Registration date
24/12/2025

Overall study status
Ongoing

Last Edited
20/02/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
This study has been designed following a James Lind Alliance Patient and Public Research Priority Setting Partnership, which identified the following question as a key research priority: “What are the best treatments to prevent and treat confusion and delirium after surgery in adults with a broken bone in the leg?” The study has been co-produced with the UK Musculoskeletal Trauma Patient and Public Involvement Group. A broken hip (hip fracture) is a very serious injury that requires surgery to repair or replace the broken bone followed by a long period in hospital to recover. Around a quarter of patients with hip fractures die within a year and those that survive have a permanent loss of quality of life. Worldwide there are 1.3 million hip fractures each year, with more than 70,000 in the UK. Around a quarter of patients who have a hip fracture have an episode of ‘delirium’ around the time of their surgery. Delirium is a condition where the patient loses awareness of themselves and their environment, and has difficulty thinking clearly. For relatives and friends, and the patient, delirium is very disturbing. The symptoms of delirium are similar to those of patients with dementia but develop over a short period and tend to vary over time. In the short-term, delirium leads to longer stays in hospital and an increased risk of complications including death. In the longer term, delirium is closely linked with an increased risk of developing dementia. Delirium is thought to be caused by inflammation in the brain. The inflammation is triggered by the injury and is thought to get worse during surgery. This study will investigate a drug called dexamethasone which is given during surgery. Dexamethasone is a commonly used anti-inflammatory drug. This study aims to decide if patients who have operations on broken hips are less likely to have delirium if we treat them with dexamethason during the operation.

Who can participate?
Patients aged over 60 years with a hip fracture, apart from the very small number of patients who do not have an operation on their hip.

What does the study involve?
Patients at approximately 8 hospitals in the UK will be approached to take part in the study. 94 participants will take part, with half being allocated by chance to receiving dexamethasone, and half to receiving standard care (no drug). Neither the patients nor their doctors will know which treatment they had to make the study fair. All other elements of the patient's treatment will follow the normal care pathway for all hip fracture patients at the hospital. Baseline information including pre-injury mobility and residential status will be collected. Participants or their proxies will also be asked to complete the EQ-5D-5L questionnaire to indicate their typical pre-injury quality of life status. A simple questionnaire called the Memorial Delirium Assessment Scale (MDAS) will be used to measure symptoms of delirium in the first five days after surgery. Participants' mobility, quality of life and complications, including the risk of infection and developing dementia in the 12 months after surgery will also be measured.
What are the possible benefits and risks of participating?
Dexamethasone is already used very widely in the NHS as a treatment for anti-sickness, but it has not been tested to see if it could help prevent delirium after surgery. Rarely a mild increase in blood sugar levels may occur, which returns to normal within 24 hours, this can be more common in people with diabetes but there is no evidence this causes any significant problems. Other reactions have only been associated with a long treatment with dexamethasone, so are not expected in this study where only a one-off dose is given.
Hip fracture surgery carries some risk, including infection in the surgical wound, blood clots, chest or urine infection. These risks are the same for people who are not part of this research project.

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

When is the study starting and how long is it expected to run for?
January 2026 to February 2027
Who is funding the study?

National Institute for Health and Care Research, Research for Patient Benefit (RfPB) programme

Who is the main contact?
Central trial team, white16-delphic@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific, Public, Principal investigator

Contact name
Prof Matthew Costa

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Additional identifiers

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

Integrated Research Application System (IRAS)
287755

Central Portfolio Management System (CPMS)
59647

National Institute for Health and Care Research (NIHR)
206655

Study information

Scientific Title
World Hip Trauma Evaluation - DELPHIC: Delirium Prevention in Hip Fracture with Corticosteroids

Acronym
WHiTE-DELPHIC

Study objectives
1. To confirm willingness of patients and healthcare professionals to participate in this randomised comparison
2. To confirm whether there is an indication of a meaningful effect in the primary outcome (peak MDAS score) of the proposed definitive randomised comparison
3. To confirm process practicality in terms of intervention delivery and data collection for a definitive randomised comparison

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/10/2025, South Central - Berkshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8178; berkshire.rec@hra.nhs.uk), ref: 20/SC/0452

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

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

Interventions
WHiTE 16-DELPHIC 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 16-DELPHIC: randomisation will be on a 1:1 basis to standard of care plus dexamethasone or standard of care, stratified by recruitment centre and the presence/absence of cognitive impairment at presentation (proxy consent will be used as a surrogate indicator for lack of cognitive impairment).
The intervention will be a single intravenous bolus of 13.2 mg dexamethasone base (equivalent to 16 mg dexamethasone phosphate) at the start of anaesthesia.
The standard care will be as per routine practice at each recruitment centre

Intervention Type
Other

Primary outcome(s)
1. Data on recruitment (dates relating to site set-up, recruitment period and numbers approached, consented and randomised). The main measure will be recruitment rate measured using number recruited divided by number of days sites are open to recruitment at end of study

Key secondary outcome(s)
1. Peak post-operative delirium measured using Memorial Delirium Assessment Scale (MDAS) at days 1-5 post-surgery

2. Pain measured using Functional Pain Scale (FPS) for use in hospitals (for participants unable to communicate due to mental capacity (estimated to be approximately 10% of the comparison sample) the validated Pain Assessment in People with Advanced Dementia (PAINAD) tool will be used) at pre-surgery and on each of the first 5 days post-surgery

3. Cognitive impairment measured using TICS UK English questionnaire at 4 months post-diagnosis of a hip fracture

4. Emotional distress measured using Distress Thermometer at the 4 month follow up time-point and asked of participants who achieved an MDAS score of 13 or higher following the surgery

5. Complications measured using medical records at at discharge and if indicated, at 4 months post diagnosis of hip fracture

Completion date
05/04/2027

Eligibility

Key inclusion criteria

As per the overarching Platform Master Protocol; all adults aged 60 years or over diagnosed with a hip fracture that in the opinion of the treating surgeon may benefit from surgical treatment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

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 DELPHIC:
1. Acute uncontrolled infection as diagnosed by the treating clinician.
2. Hypersensitivity to dexamethasone or excipients within the preparation
3. Use of oral or / intravenous corticosteroids at or following admission.
4. Concurrent participation in a conflicting clinical trial of an investigational medicinal product
5. Receipt of a live vaccine within 2 weeks prior to treatment
6. Known gastrointestinal ulcer
7. Congestive cardiac failure
8. History of steroid psychosis
9. Current glaucoma or corneal ulcer
10. Severe ulcerative colitis
11. Active diverticulitis
12. Suspected or confirmed strongyloidiasis
13. Known history of tuberculosis

Date of first enrolment
18/02/2026

Date of final enrolment

05/02/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
George Eliot Hospital
Lewis House
College Street
Nuneaton
England
CV10 7DJ

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 will be available upon request from the Lead Investigator (Prof. Matt Costa, matthew.costa@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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	11/09/2025	19/12/2025	No	No