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# Does continuous arterial blood pressure monitoring during surgery benefit patients who are high risk, particularly those who are older and living with frailty?


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|---|---|---|
| **Submission date**<br>10/07/2025 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>09/09/2025 | **Overall study status**<br>Ongoing | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>17/12/2025 | **Condition category**<br>Surgery | [_] Individual participant data<br>[X] Record updated in last year |


## Plain English summary of protocol

Background and study aims
Many people have low blood pressure during surgery, which can be harmful, especially for older or frail patients. This can affect important organs like the heart, kidneys, or brain. One way to help is by measuring blood pressure continuously during surgery using a drip in the wrist, instead of checking it every few minutes with a cuff. This might help doctors spot and treat low blood pressure more quickly. However, this method isn't used often because there isn't enough research to support it. This study aims to find out if continuous blood pressure monitoring during surgery helps high-risk patients, especially those having surgery for a broken hip.

Who can participate?
The study is for people aged 65 or older who are considered frail and need surgery for a broken hip.

What does the study involve?
Participants will be randomly placed into one of two groups. One group will have their blood pressure measured continuously during surgery using a drip in the wrist. The other group will have it measured at regular intervals using a cuff. Researchers will look at how well the study works, track blood pressure during surgery, check for any complications, and ask patients about their quality of life afterward.

What are the possible benefits and risks of participating?
The study may help improve care for future patients by showing whether continuous blood pressure monitoring is better. There may be some small risks from the drip used for monitoring, such as discomfort or infection, but these are rare and will be carefully managed.

Where is the study run from?
South Tees Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
The study started in June 2025 and is expected to run until April 2028.

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Andrew Kane, andrew.kane@nhs.net

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Mr Andrew Kane

### ORCID ID
https://orcid.org/0000-0001-9488-4086

### Contact details
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW
+44 7709619017
andrew.kane@nhs.net

# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
351284

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
R&D 24/006, CPMS 65485

# Study information

### Scientific Title
Continuous ARterial monitoring in Elderly and Frail patients for hip fractUre surgery to prevent Low blood pressure

## Acronym
CAREFUL

## Study objectives
1. To undertake a systematic review and meta-analysis to understand what is currently known regarding the use of continuous blood pressure monitoring and its impact on intra-operative hypotension and associated morbidity.
2. To understand clinician attitudes towards continuous arterial monitoring in older frail patients presenting for trauma surgery through questionnaires and focus groups.
3. To undertake a feasibility study with embedded qualitative research to assess whether a full-scale randomised controlled trial (RCT) of continuous invasive arterial blood pressure monitoring versus standard care is feasible in the older, frail patient population presenting for hip fracture surgery.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 15/09/2025, Wales REC 7 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 941107, 2922 940968; Wales.REC7@wales.nhs.uk), ref: 25/WA/0235

## Study design
A feasibility study consisting of an external multi-centre two-arm parallel-group assessor-blinded randomized pilot trial with a nested qualitative study

## Primary study design
Interventional

## Study type(s)
Prevention, Safety

## Health condition(s) or problem(s) studied
Continuous invasive arterial blood pressure monitoring during orthopaedic trauma surgery

## Interventions
Study arms
Participants will be randomly allocated in a 1:1 ratio using block randomisation, stratified by site to either:
Continuous invasive arterial blood pressure monitoring
• Up to three attempts to establish continuous invasive arterial blood pressure monitoring using local anaesthesia before general or neuraxial anaesthesia.
• Continuous arterial blood pressure monitoring will be maintained until the patient reaches the recovery room, where it may be discontinued or continued at the discretion of the clinical team.
OR
Standard care
• 3-to-5-minute cycles of blood pressure monitoring.

Duration of treatment
Start: From the start of anaesthesia care.
End: The randomised treatment can be removed at a point the clinician feels is appropriate- normally in the recovery room.

Follow-up period
120 days from the day of surgery.

Randomisation
The randomisation schedule will be stratified by site and formed of randomly permuted blocks of randomly varying size using a 1:1 allocation ratio. The allocation sequence will be generated by a statistician not involved in the study and uploaded to the REDCap platform.
Following consent, randomisation will be performed immediately via the REDCap platform. Clinical teams will be informed as early as possible to allow planning of care.

## Intervention Type
Procedure/Surgery

## Primary outcome(s)
Feasibility outcomes:
1. Site setup is measured using number of sites recruiting first participant at end of trial
2. Participant recruitment rate is measured using number of participants recruited per site per month at end of trial
3. Outcome follow-up data completeness is measured using proportion of participant-reported outcome data collected at 120 days
4. Intervention compliance is measured using proportion of participants receiving allocated treatment at end of trial
5. Treatment crossover is measured using proportion of patients not receiving allocated treatment at baseline and during hospital stay
6. Unblinding rate is measured using number of outcome assessors unblinded to trial allocation at 120 days

## Key secondary outcome(s))
Feasibility of data collection of clinical and patient-reported outcome measures:
1. Pre-injury mobility is measured using patient or carer report at baseline
2. Pre-injury quality of life is measured using EuroQol EQ5D5L questionnaire at baseline
3. Pre-injury residential status is measured using patient or carer report at baseline
4. Delirium is measured using 4AT tool at baseline and on day 3 (+/-1 day) post-surgery
5. Comorbidities are measured using patient notes at baseline
6. Drug history is measured using patient notes at baseline
7. Routine blood test results are measured using full blood count, urea and electrolytes, clotting screen, CRP at baseline
8. Blood pressure is measured using standard clinical measurement on admission
9. ASA score is measured using anaesthetic chart at time of surgery
10. Type of anaesthetic is measured using anaesthetic chart at time of surgery
11. Volume of fluids administered is measured using anaesthetic chart during surgery
12. Units of blood products administered is measured using anaesthetic chart during surgery
13. Vasopressor and inotrope use is measured using anaesthetic chart during surgery
14. Estimated blood loss is measured using anaesthetic chart during surgery
15. Cardiac arrest is measured using anaesthetic chart during surgery
16. Death in theatre is measured using anaesthetic chart during surgery

17. Intra-operative blood pressure is measured using uploaded intra-operative measurements during surgery
18. First blood pressure in recovery is measured using standard clinical measurement in recovery room
19. Postoperative complications are measured using Comprehensive Complications Index at 120 days
20. Discharge destination is measured using patient notes at time of hospital discharge
21. Residential status is measured using patient or carer report at 120 days post-surgery
22. Mobility is measured using patient or carer report at 120 days post-surgery
23. Quality of life is measured using EuroQol EQ5D5L questionnaire at 120 days (+/-7 days) post-surgery

### Completion date
01/04/2028

## Eligibility

### Key inclusion criteria
1. ≥65 years old
2. Clinically frail – assessed as a Clinical Frailty Scale (CFS) Score of 5 or more
3. Primary proximal hip fracture (fractured neck of femur)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Senior

### Lower age limit
65 years

### Upper age limit
120 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Planned continuous arterial blood pressure monitoring or use of non-invasive blood pressure monitoring at a high frequency
2. Refusal to consent

### Date of first enrolment
01/10/2025

**Date of final enrolment**
01/10/2027

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**South Tees Hospitals NHS Foundation Trust**
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

# Sponsor information

**Organisation**
South Tees Hospitals NHS Foundation Trust

**ROR**
https://ror.org/02js17r36

# 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
All data generated or analysed during this study will be included in the subsequent results publication

### IPD sharing plan summary
Published as a supplement to the results publication

### 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 |