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# Trial of local anaesthetic nerve blocks for hip fracture pain relief in prehospital care, compared to usual care (morphine), given by paramedics

**Submission date**
05/11/2020

**Recruitment status**
No longer recruiting

**Registration date**
22/09/2021

**Overall study status**
Completed

**Last Edited**
19/08/2022

**Condition category**
Musculoskeletal Diseases

[X] 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
Hip fractures are a very common injury for elderly people. About one in three patients who break their hip die within one year and many patients lose mobility and independence. Pain relief before the patient reaches hospital is often inadequate and causes side effects which may slow down recovery. We have recently completed a small study testing whether a local anaesthetic injection into the hip area called Fascia Iliaca Compartment Block (FICB) given by paramedics at the scene of injury is safe and acceptable. We met all the criteria that we set at the beginning of the study, and concluded that it is feasible to undertake a full trial.

Aim
We aim to find out whether the local anaesthetic injection reduces pain, is safe, and improves patient health outcomes, as well as how much it costs the National Health Service (NHS).

Who can participate?
Adult patients attended by a participating study paramedic following a 999 call who are assessed as having an isolated hip fracture.

What does the study involve?
We will carry out a trial where paramedics give patients either the new treatment - local anaesthetic injection or usual care (often morphine). Patients will be allocated to one or other treatment by a random process (similar to tossing a coin) to ensure a fair comparison between treatments.
We will provide training for the paramedics who take part in the trial, so that they can perform the local anaesthetic injection safely. When a trained paramedic attends a patient he or she assesses as having a hip fracture, (s)he will use a scratchcard to decide which treatment to give the patient. We will compare patients' pain levels, other outcomes and costs between those allocated to the new local anaesthetic injection and those allocated to receive usual care. The other outcomes we will compare between the two groups during their initial care and up to four

months following injury are: length of stay in hospital, deaths, quality of life, ability to walk, and satisfaction with care. We will also monitor safety by identifying any concerning health-related events in each group. We will work out the costs of NHS care in each group.

What are the possible benefits and risks of participating?
The possible benefits of taking part are potentially receiving more effective pain relief at the time of hip fracture. The risks of taking part - there are some potential complications of the local anaesthetic nerve block, including infection or bruising at the site of the injection. Rarer complications include nerve damage and local anaesthetic toxicity. Although there are potential complications, current usual care (morphine) also has several known side effects including confusion, nausea, constipation and respiratory depression - the patient will avoid these side effects.

Patient and public involvement
Two members of the public have helped us to plan this bid and two patient groups (approximately 40 individuals) reviewed our ideas. Members of the public will continue to be involved throughout this research. During the research, members of the public will attend meetings, help to write information sheets for patients, and help to write up the findings from this research. Members of the public will also sit on our oversight committee to ensure the research is carried out properly, and be part of local implementation teams at sites to ensure the patient voice is heard throughout our research.

Where is the study run from?
Swansea University and areas within five ambulance services in England and Wales.

When is the study starting and how long is it expected to run for?
June 2020 to January 2025.

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

Who is the main contact?
Dr Jenna Jones
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# Contact information

### Type(s)
Public

### Contact name
Dr Jenna Jones

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
291853

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 47827, NIHR 129972, IRAS 291853

# Study information

### Scientific Title
Randomised trial of clinical and cost effectiveness of Administration of Prehospital fascia Iliaca compartment block for emergency hip fracture care Delivery (RAPID2)

### Acronym
RAPID2

### Study objectives
FICB provides better pain relief for patients with hip fracture in prehospital care than morphine

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Multi-site parallel group superiority randomized trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Community

### Study type(s)

Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

## Health condition(s) or problem(s) studied
Pain relief of patients with hip fracture in prehospital care

## Interventions
Usual care
Currently, when a patient who has called 999 is attended by a paramedic for a suspected hip fracture, the paramedic clinically assesses the patient, takes their history, examines them and records observations (blood pressure, heart rate, respiratory rate, oxygen saturations, Glasgow Coma Scale, patient reported pain score and temperature). Paramedics cannulate patients and provide IV fluids and/or oxygen, as appropriate, based on clinical parameters. They are currently able to provide systemic analgesia only, most commonly opioids (IV morphine), paracetamol and Entonox. In RAPID 2, patients allocated to usual care, will receive this care.

Intervention care
If the patient is randomly allocated to the intervention arm, the paramedic will administer FICB in addition to basic usual care as described above, but avoiding use of opioids. The FICB will utilise 1% Prilocaine and will follow the method used in the RAPID feasibility study (http://www.isrctn.com/ISRCTN60065373) (based on Dalens et al 1989). The paramedic will still provide the patient with paracetamol and Entonox but should not give the patient morphine for at least 20 minutes after the patient has received the FICB (to allow for the time of onset of Prilocaine). If, however, the FICB does not relieve the patient's pain after 20 minutes, the paramedic would be able to give the patient morphine if judged appropriate (‘rescue morphine’).

Random allocation is carried out using sequentially numbered unique scratchcards, out of the sight of the patient. Both study arms will be followed up at one and four months.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
1% Prilocaine

## Primary outcome measure
Pain measured using an eleven point numeric rating scale (0-10) pre-randomisation and on arrival at the emergency department

## Secondary outcome measures
1. Routine data taken from patient records:
1.1. Ambulance service job cycle time (from 999 call to ‘ambulance free’)
1.2. Analgesia and anti-emetics administered prehospitally, including morphine and ‘rescue morphine’
1.3. Length of stay in hospital, ITU and residential rehabilitation care following injury

1.4. Subsequent ED attendances and emergency admissions
1.5. Mortality
1.6. Diagnosis (for patients who did not have a hip fracture)
1.7. Where patient was admitted from and discharged to
2. Patient-reported outcomes:
2.1. Satisfaction with care (Quality of Care Monitor at one month)
2.2. Health related quality of life (HRQoL) (EQ-5D-5L at one and four months)
2.3. Mobility (Rivermead Mobility Index at one and four months. One question will be removed to enable to patient to complete the questionnaire by themselves)
3. Costs to the NHS: This includes all the costs (excluding research costs) sustained to deliver the intervention. A purposely designed data collection questionnaire tested in the feasibility study will be sent to each recruiting site at the end of the study

### Overall study start date
10/06/2020

### Completion date
31/01/2025

## Eligibility

### Key inclusion criteria
Adult patients attended by a participating study paramedic following a 999 call who are:
1. Assessed as having an isolated hip fracture – hip fracture assessment checklists will be provided to aid recognition
2. Conscious (Glasgow Coma Scale Score of ≥13)
3. Haemodynamically stable
4. To be conveyed to a participating receiving hospital

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
1,404

### Key exclusion criteria
1. Taking anticoagulants
2. Have a hip prosthesis on the affected side
3. Refuse analgesia
4. Are thought to be having a stroke
5. Are combative
6. Are attended by a paramedic working alone

### Date of first enrolment

01/10/2021

**Date of final enrolment**
30/09/2023

# Locations

**Countries of recruitment**
England

United Kingdom

Wales

**Study participating centre**
**East of England Ambulance Service**
United Kingdom
SG8 6EN

**Study participating centre**
**East Midlands Ambulance Service**
United Kingdom
NG8 6PY

**Study participating centre**
**South East Coast Ambulance Service**
United Kingdom
RH10 9BG

**Study participating centre**
**South West Ambulance Service**
United Kingdom
EX2 7HY

**Study participating centre**
**Welsh Ambulance Service**
United Kingdom
LL17 0LJ

**Study participating centre**
**Addenbrooke's Hospital**
Hills Road
Cambridge
United Kingdom
CB2 0QQ

**Study participating centre**
**Queen's Medical Centre**
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

**Study participating centre**
**Royal Devon and Exeter Hospital**
Royal Devon and Exeter NHS Hospital Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

**Study participating centre**
**Royal Surrey County Hospital**
Royal Surrey County Hospital NHS Foundation Trust
Egerton Road
Guildford
United Kingdom
GU2 7XX

**Study participating centre**
**Morriston Hospital**
Heol Maes Eglwys
Morriston
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

# Sponsor information

### Organisation
Swansea University

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### Sponsor type
University/education

### Website
http://www.swansea.ac.uk/

### ROR
https://ror.org/053fq8t95

## 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
Results will be published in a high impact peer-reviewed journal.

## Intention to publish date
01/02/2025

## Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

## IPD sharing plan summary
Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 17/08/2022 | 19/08/2022 | Yes | No |