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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
j.k.jones@swansea.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Jenna Jones

ORCID ID
https://orcid.org/0000-0002-1280-4941

Contact details
ILS2 Singleton Campus
Swansea University
Swansea
United Kingdom

SA2 8PP
+44 (0)1792513424
j.k.jones@swansea.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
291853

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

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

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