ISRCTN60065373 https://doi.org/10.1186/ISRCTN60065373

RAPID: Fast pain relief for hip fracture: a study with paramedics.

Submission date	Recruitment status	[X] Prospectively registered
05/11/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/11/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/12/2022	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Breaking a hip is very painful. Patients who break their hip will often call 999 and be taken to hospital by an ambulance. Sadly, research has shown that paramedics do not always give patients with a broken hip adequate pain relief. Fascia iliaca compartment block (FICB) has been tested in a few small studies recently. It has been shown to be a safe and effective method of giving pain relief to patients with hip fracture. FICB involves finding a soft tissue ‘compartment’ which lies over the hip. This is done using bony landmarks and feeling resistance from a needle. The person giving the FICB will feel two 'pops' as the needle goes through two tissue layers (fascias). Local anaesthetic is then injected into this ‘compartment’ with the aim of blocking sensation to three nerves in this area (femoral, obturator, lateral femoral cutaneous). The patient will then not be able to feel pain from their hip. This study involves paramedics giving FICB to some patients who break their hip. It is possible that FICB could give better pain relief to patients who break their hip than what patients are given in current practice (usually morphine). FICB could also reduce the amount of morphine given to patients who break their hip. This would benefit patients because morphine has several side effects (feeling sick, giddy or confused, being constipated or having trouble breathing). This study will also investigate whether FICB has any long term benefits by comparing death rates, general health and mobility of patients 30 days after the injury. It will also look at whether it would be possible and worthwhile to carry out a bigger trial involving a number of trial participating centres.

Who can participate?
Adult patients assessed by a paramedic as having a hip fracture.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given standard pain relief (usually morphine). Those in group 2 are given FICB. If the FICB does not work within 15-20 minutes, they may also be given morphine. All participants can be given paracetamol and Entonox (other types of painkillers) as required. Once they reach the hospital, a nurse asks them to assess their pain levels by giving a score between 0 (no pain) to 10 (worst pain imaginable). All patients are then followed up 30 days later to record the number of people who have died, their general state of health and how mobile they now are after the fracture.

What are the possible benefits and risks of participating?
Trial participants who receive the local anaesthetic injection instead of morphine may benefit from superior pain relief or better long term outcomes as a result of taking part in the trial, but we do not know for sure – that is why we are carrying out this research. There are risks of having a local anaesthetic injection such as nerve damage (short term or long term) and bleeding, which are rare. A more common side effect is bruising around the site of the injection.

Where is the study run from?
Swansea University (UK)

When is the study starting and how long is it expected to run for?
October 2015 to September 2017

Who is funding the study?
Health and Care Research Wales

Who is the main contact?
Dr Jenna Bulger

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
Rapid Analgesia for Prehospital Hip Disruption (RAPID): a feasibility study for a randomised controlled trial

Acronym
RAPID

Study objectives
We hypothesise that it is feasible to undertake a randomised controlled trial (RCT) to test the clinical and cost-effectiveness of paramedics providing FICB (fascia iliaca compartment block) as early pain relief to patients who have fractured a hip at the scene of their injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 6, 07/01/2016, ref: 15/WA/0439

Study design
Feasibility study for a randomised controlled trial, conducted in a single site

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Patients with hip fracture, in the prehospital environment

Interventions
Participants are randomly allocated to one of two groups.
1. Group 1: Patients receive standard treatment and given normal pain relief (usually morphine)
2. Group 2: Patients receive fascia iliaca compartment block (FICB). If the FICB has not relieved the patient's pain after 15-20 minutes, the paramedic will also be able to give them morphine.
Patients in both groups can be given paracetamol and Entonox as required, as is current practice. A pain score will be taken by the triage nurse when the patient arrives at the emergency department. The patients will then be followed up at 30 days to record death rates, health status and patient mobility.

Training will be provided for the paramedics taking part in the trial, so that they can perform the FICB safely and appropriately. This will involve:
1. E-learning
2. Group teaching sessions

3. Attending the local hospital in pairs to perform FICB on patients who require them (under the supervision of an anaesthetist).
The paramedics will identify patients with suspected hip fractures. The patient will be asked to give a pain score on a scale from zero to ten. Zero is no pain at all and ten is the worst pain ever. For patients who cannot express their pain score due to disability or dementia, a different pain score will be used (the Adapted Abbey Scale). The paramedic will then open a sealed opaque envelope containing a computer generated random number. This will decide whether the patient is given intervention or control treatment.

There will also be interviews with patients and focus groups with paramedics to find out whether FICB is acceptable to paramedics who are performing it, and to patients who are receiving it.

Intervention Type
Procedure/Surgery

Primary outcome measure
Our feasibility study objectives are as follows: to assess
1. Accuracy, in particular specificity, of recognition of hip fracture by paramedics in order to establish appropriate and safe delivery of the intervention.
2. Willingness of both patients and paramedics to participate in the study.
3. Compliance with the intervention by paramedics.
4. Sample size required for a full RCT, and recruitment period required to achieve target.
5. Acceptability of the method of providing pain relief in the prehospital care of patients with hip fracture.
6. Which outcome measures should be used in a full RCT and at what point they should be recorded. Proposed outcomes measures to be tested are:
6.1. Self-reported pain level using numeric rating scale of 0- 10 with 0 being no pain at all and 10 being the worst pain imaginable. This will be recorded immediately before pain relief is given and repeated on arrival at the hospital by the triage nurse (before they know which pain relief the patient received).
6.2. Patient satisfaction with the care they received from paramedics using a modified Quality of Care Monitor. This will be measured when the NHS researcher takes consent to participate in the trial at approximately 7-10 days after the patient's injury
6.3. Complications of FICB (Patient safety – adverse events (AE) and serious adverse events (SAE) will be recorded)
6.4. Length of time that the paramedics were with the patient (in order to determine whether providing FICB has a significant effect of delaying the paramedics)
6.5. Requirement of antiemetics and alternative analgesia
6.6. Length of stay
6.7. Mortality at 30 days and/or at six months
6.8. Time from admission to surgery
6.9. Health related quality of life, using SF12 at 30 days and/or at six months
6.10. Mobility score, using the Rivermead index at 30 days and/or at six months
7. Whether or not it is feasible and warranted to carry out a full, multi-centre trial, as indicated by our progression criteria, all of which must be met within reasonable limits:
7.1. Paramedic recognition of hip fractures have a sensitivity of 60% or more and a specificity of 90% of more
7.2. Ability to recruit ten paramedics to the trial
7.3. 80% or more of eligible patients consent to treatment in the intervention arm
7.4. Consent to follow up 60% or more

7.5. Follow up data for primary outcomes can be collected for 70% or more of patients
7.6. Mean patient satisfaction in intervention group is not less than 80% of patient satisfaction in the control group
7.7. Feasibility trial findings indicate that we remain in equipoise about the effectiveness of paramedic administered FICB (i.e. that pain scores before pain relief and on arrival at hospital has a difference of less than 50% between intervention and control groups)
7.8. Adverse event rate (e.g. arterial puncture or infection at the site of FICB) of less than 5%

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2015

Completion date
30/09/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Patients who are assessed by a paramedic as having a hip fracture (paramedics will make this assessment by using a hip fracture diagnosis checklist tool)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
71

Key exclusion criteria
1. Patient refuses to participate
2. Patient is combative
3. Patient has an allergy to local anaesthetic
4. Patient is receiving coagulopathy (use of warfarin, clopidogrel or ‘new’ anticoagulants)
5. Patient has any other distracting injury (i.e. has pain in a different place, which would make taking pain scores for only the hip difficult)
6. Patient has decreased level of consciousness (Glasgow Coma Scale score of less than 14)

7. Patient is haemodynamically unstable
8. Patient has neurovascular damage to the affected leg
9. Patient has received previous femoral bypass surgery
10. Patient has an infection at the site of insertion of the injection
11. The paramedic is unable to palpate the femoral artery on the affected leg
12. Patients who appear to have body mass of less than 50kg (A 50kg patient could safely be given 6ml/kg of 1% prilocaine. By only using 30ml of the local anaesthetic, we will have a margin of safety to avoid patients developing local anaesthetic toxicity).

Date of first enrolment
01/05/2016

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Swansea University
ILS2, Singleton Campus
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Sponsor information

Organisation
Welsh Ambulance Services NHS Trust

Sponsor details
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Sponsor type
Other

ROR
https://ror.org/017qpw206

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Results and Publications

Publication and dissemination plan
Planned publication of trial protocol, a paper about training paramedics to provide FICB in the emergency prehospital environment and a qualitative and quantitative results paper.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/01/2017		Yes	No
Results article	results	12/06/2019	19/06/2019	Yes	No
Results article	results	15/02/2019	30/03/2020	Yes	No
Results article	results	19/12/2019	04/01/2021	Yes	No
Other publications	Use of scratchcards for allocation concealment	12/09/2018	01/12/2022	Yes	No
HRA research summary			28/06/2023	No	No