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Morphine or iv paracetamol in acutely injured neck of femur fractures

Submission date
04/12/2017

Recruitment status
Stopped

Registration date
12/01/2018

Overall study status
Stopped

Last Edited
11/04/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Fractured neck of femur, also known as fractured hip, is an extremely painful condition requiring rapid pain relief. In the UK, 70,000 patients, predominantly elderly, are treated in hospital emergency departments annually for fractured hips, often following falls. Pain relief treatments for a fractured hip currently include morphine or paracetamol delivered into the bloodstream. Whilst morphine offers pain relief, it can cause side-effects including nausea, vomiting, breathing difficulties and low blood pressure. These side-effects are common among elderly patients. Morphine is also a controlled drug and may cost more to administer as it requires presence of 2 staff members when authorising its use. Furthermore, morphine may require additional costly resources and medications to manage its side-effects. When paracetamol is delivered into the bloodstream it is thought to have similar pain relief and fewer side-effects than morphine in treatment for several conditions. Therefore, current guidelines instruct use of paracetamol delivered into the bloodstream for pain relief for patients with a fractured hip. However, most emergency departments use morphine because there is no high-quality evidence to support the guidelines. The aim of this study is to provide this evidence by performing a trial to assess whether use of paracetamol is not inferior to morphine for pain relief and causes fewer side-effects in patients with a fractured hip. This study will provide high-quality evidence to support the most effective management of pain for a fractured hip.

Who can participate?
Adults aged 18 and older who have a suspected fracture neck of the femur.

What does the study involve?
Participants are randomly allocated to receive either paracetamol or morphine and within the two hours following treatment, the team assesses patient-reported pain relief, side-effects, requirement for additional pain relief, blood pressure pulse rate, respiratory rate and blood oxygen levels. The cost-effectiveness of each treatment will also be assessed by looking at costs of giving the drugs and resources and medications needed to manage the side-effects of each drug.

What are the possible benefits and risks of participating?
There is not expected to be any direct benefits or risks for taking part in the study as both

treatments are used in normal clinical care for pain relief in patients with fractured hips. However, it is hoped that this trial will be able to give further information about the best treatment to give to these patients.

Where is the study run from?
Royal Stoke University Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2017 to January 2020

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2017-003875-77

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36716

Study information

Scientific Title
A randomised, controlled double blinded non-inferiority trial of intravenous morphine compared with intravenous paracetamol for pain relief in patients presenting to the emergency department with suspected acute fractured neck of femur

Study objectives
The aim of this study is to assess whether use of paracetamol is not inferior to morphine for pain relief and causes fewer side-effects in patients with a fractured hip.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber – Leeds East Research Ethics Committee, 05/12/2017, ref: 17/YH/0404

Study design
Randomised; Interventional; Design type: Treatment, Drug

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Fractured neck of femur, also known as fractured hip

Interventions
Patients are given either IV paracetamol or IV morphine and within the 2 hours following treatment. The team assesses patient-reported pain relief, side-effects, requirement for additional pain relief, blood pressure pulse rate, respiratory rate and blood oxygen levels. There are no further follow-up other than noting length of hospital stay.

The cost-effectiveness of each treatment is also assessed by looking at costs of giving the drugs and resources and medications needed to manage the side-effects of each drug.

Intervention Type
Other

Phase

Phase IV

Primary outcome measure
Pain is measured using a 100mm visual analogue scale (VAS) at 0, 15, 30, 60 and 120 minutes.

Secondary outcome measures
1. The number of adverse events, type, severity and seriousness are measured by patient report or measurement of blood pressure, pulse rate, respiratory rate and blood oxygen levels within the 120 minutes
2. The requirement for and amount of rescue analgesia required within the 120 minutes are recorded on the patient notes and study case report form
3. Generic health status is measured by completion of EQ-5D at baseline and 120 minutes
4. The cost of IV paracetamol and IV morphine in fractured Neck Of Femur patients is measured in terms of pain relief and adverse events (measured as above), including the cost of the drugs and their administration, and requirement for additional drugs and resources in management of side effects

Overall study start date
11/07/2017

Completion date
31/01/2020

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. 18 years of age and above
2. Clinical suspicion of a fractured neck of femur
3. The patient has given informed consent or this has been gained from either the Personal or Professional Legal Representative

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 338; UK Sample Size: 338

Key exclusion criteria

1. There is clinical suspicion that the patient has other fractured bones
2. The patient has had any form of hip replacement on the affected side
3. Glasgow Coma Scale less than 14
4. Paracetamol or morphine has been received in the last 4 hours
5. Known allergy to morphine or paracetamol
6. Contraindications for IV morphine or paracetamol (as detailed in the product SmPC)
7. Pre-diagnosed liver disease
8. Known pregnancy

Date of first enrolment
01/04/2018

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Staffordshire
Stoke-on-Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
University Hospitals of North Midlands NHS Trust

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Newcastle Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03g47g866

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
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/02/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from academic.research@uhnm.nhs.uk. Core data will be available immediately after main publication. A data request form is required to be completed and must outline the type of data to be obtained, the reason for obtaining this data (research question / objective), the timing for when the data is required to be available (start date/end date). Checks will be performed by the Quality Assurance Steering Group to ensure that the data set requested is appropriately suited to answer the research question/objective and that the request fits with the original ethical approval and participant consent and adheres to funder and legal restrictions. Only de-identified data are available for request in aggregated format or at the level of the individual participant.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No