

# Morphine or iv paracetamol in acutely injured neck of femur fractures

<b>Submission date</b> 04/12/2017	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/01/2018	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/04/2019	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Dr Liz Hartshorne (Scientific)

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## Contact information

### Type(s)

Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2017-003875-77

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

United Kingdom

England

## 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

## 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

# Results and Publications

## 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](mailto: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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes