

Fractured Hip Infection Trial: FHIT- low vs. high dose antibiotic impregnated cement in the treatment of patients with fractured neck of femur

| | | |
|--|---|--|
| Submission date 06/12/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 21/03/2013 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 18/10/2018 | Condition category Injury, Occupational Diseases, Poisoning | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

We are carrying out a study on patients who have sustained a fractured hip in order to compare different doses of antibiotics within the cement at the time of hip surgery. Our goal is to establish if adding a higher dose of antibiotics into the cement will reduce the rate of surgical site infection. We will look at a number of patient characteristic such as age, gender, rates of infection, timing of surgery, and other characteristics. The study's findings should help to improve the well being of patients with a fractured hip in the UK and to enhance the country's research base in orthopaedic infection.

Who can participate?

The study aims to recruit about 850 patients, aged above 18 years old, from the Northumbria NHS Trust (UK) who have sustained a fractured hip.

What does the study involve?

Patients will be randomly allocated to one of two groups. Randomisation, which is like a coin toss, will allocate the antibiotic cement given to the patient. Group 1 will receive low antibiotic dose cement (that is used in normal practice) and group 2 will receive high antibiotic dose cement (that is used in other forms of hip surgery in normal practice). Both groups will then have the same postoperative care and follow up. At the end of the study, we will compare the rates of surgical site infection between the groups. Patients will be given the same clinical care whether they are in group 1 or 2.

What are the possible benefits and risks of participating?

Risks include those normally associated with an operation and will be discussed at the time of the operation. The study may lead to a positive change in treatment for this operation in the NHS. There may be no differences between the two groups.

Where is the study run from?

The study has been set up by the Northumbria NHS Trust (UK).

When is the study starting and how long is it expected to run for?

Recruitment started in July 2008. Participants will be enrolled until the target number of 850 is reached.

Who is funding the study?

A small amount of educational funding has been supplied by Heraeus Medical (UK).

Who is the main contact?

Mr Mike Reed, mike.reed@nhs.net

Mr Andrew Sprowson, apsprowson@gmail.com

Contact information

Type(s)

Scientific

Contact name

Mr Mike Reed

Contact details

Northumbria Healthcare NHS Foundation Trust

Research and Development

North Tyneside General Hospital

Rake Lane

North Shields

United Kingdom

NE29 8NH

-

mike.reed@nhs.net

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Low vs. high dose antibiotic impregnated cement in the treatment of patients with fractured neck of femur: a two arm assessor blinded randomised controlled trial

Acronym

FHIT

Study objectives

It is hypothesised that high dose antibiotic impregnated cement will reduce the rates of surgical site infection in patients undergoing a hip hemiarthroplasty for fractured neck of femur vs. standard of care low dose antibiotic impregnated cement.

The null hypothesis is that there will be reduction in surgical site infection between treatment groups.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee Newcastle & North Tyneside 2 Research Ethics Committee, 16 July 2008, ref: 07/H0901/63

Study design

Twin site two arm assessor blinded randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Fracture of neck of femur / Surgical site infection / orthopaedic

Interventions

In this pragmatic trial, patients will undergo emergency hip hemiarthroplasty (cemented) using the standard technique of the anaesthetist and the operating surgeon. In addition, the patient will undergo one of the two peri-operative cements:

Usual best standard: Standard cement used to cement the hip hemiarthroplasty into the femur, which contains 0.5g of gentamicin. No technique modification is needed.

Intervention: Revision cement used to cement the hip hemiarthroplasty into the femur, which contains 1g gentamicin and 1g of clindamycin. No technique modification is needed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Deep surgical site infection as defined by the Health Protection Agency

Key secondary outcome(s)

1. Superficial surgical site infection as defined by the Health Protection Agency
2. Length of stay
3. Surgeon grade will be documented as consultant orthopaedic surgeon, specialist trainee or core training doctor.

4. Admission to high dependency unit
5. All complications will be recorded

All baseline data will be summarised descriptively by treatment group.

Completion date

01/04/2013

Eligibility

Key inclusion criteria

All trauma orthopaedic patients (age 18 and over) who require a hip hemiarthroplasty for a fractured neck of femur will be included in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Patients under 18

Date of first enrolment

01/07/2008

Date of final enrolment

01/04/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Northumbria Healthcare NHS Foundation Trust
North Shields

United Kingdom
NE29 8NH

Sponsor information

Organisation

Northumbria Healthcare NHS Foundation Trust (UK)

ROR

<https://ror.org/01gfeyd95>

Funder(s)

Funder type

Industry

Funder Name

Heraeus Medical GmbH (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Results article | results | 01/11/2016 | | Yes | No |
| Protocol article | protocol | 17/12/2013 | | Yes | No |