ISRCTN25633145 https://doi.org/10.1186/ISRCTN25633145

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

Registration date
21/03/2013

Overall study status
Completed

Last Edited
18/10/2018

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes