

Northumbria Arthroplasty Suture Study (NASS) - A randomised trial comparing standard suture vs. triclosan (antibacterial action) coated suture on rates of surgical site infection

Submission date 04/02/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/03/2013	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 04/10/2018	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 of patients who are undergoing an elective hip or knee replacement to compare different sutures used to close the surgical site wound. Our goal is to establish if the use of a triclosan coated suture 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 undergoing a hip and knee replacement in the UK, England and enhance the country's research base in orthopaedic infection.

Who can participate?

The study aims to recruit about 2600 patients, age > 18 years from 3 centers within Northumbria NHS trust. This study is based in a hospital setting.

What does the study involve?

Patients will be invited to participate in a study comparing two different sutures hip and knee replacement. Patients will be assigned to one of two groups. A process called randomisation, which is like a coin toss, will allocate the suture given to the patient based on a monthly assignment.

Group 1 will receive a standard suture (that used in normal practice) and group 2 will receive triclosan-coated (antibacterial action) suture (that is used in other areas of surgical practice). Both groups 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 or not they are in the study.

What are the possible benefits and risks of participating?

The benefits of the study will potentially develop a positive change in treatment for this operation in a rigorous scientific manner. This may ultimately change management for this fracture in the NHS. There may be no difference in either group.

The risk is deemed low and is essentially the risks normally associated with operative intervention.

Where is the study run from?

The study has been set up and is sponsored by Northumbria NHS trust UK.

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

Recruitment started in May 2008 and follow up is expected to complete by December 2013. Participants will be enrolled on the study until around 2600 patients have been enrolled.

Who is funding the study?

Johnson & Johnson Medical Ltd, UK

Who is the main contact?

Mr Mike Reed, mike.reed@nhs.net

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Standard vs. triclosan coated suture in patients undergoing hip and knee replacement: an assessor blinded randomised controlled trial

Acronym

NASS

Study objectives

It is hypothesised that triclosan (antibacterial) coated sutures will reduce the rates of surgical site infection in patients undergoing total hip and knee replacement vs. standard of care suture.

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 Gateshead and South Tyneside Research Ethics Committee, 4th January 2008, ref: 07/H0901/62

Study design

Three site two arm assessor blinded randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgical site infection / orthopaedics / hip replacement / knee replacement

Interventions

1. Wounds closed with triclosan (antibacterial) coated suture.
2. Standard, with no technique modification needed.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Triclosan

Primary outcome(s)

Superficial surgical site infection as defined by the Health Protection Agency (England)

Key secondary outcome(s)

1. Deep surgical site infection as defined by the Health Protection Agency (England)
 2. Length of stay
 3. Surgeon grade- consultant orthopaedic surgeon, Specialist trainee or core training doctor
 4. Admission to high dependency unit
 5. 30 and 90 day mortality
 6. All complications will be recorded
 7. A cost analysis will be performed.
- All baseline data will be summarised descriptively by treatment group.

Completion date

01/04/2013

Eligibility

Key inclusion criteria

1. Being listed for a total hip or knee replacement by an orthopaedic consultant working at the Trust.
2. Participants must be willing to provide fully-informed consent, or fulfil the above criteria.
3. All patients aged 18 and above, either sex, who require a total hip or knee replacement 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

01/05/2008

Date of final enrolment

01/04/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Wansbeck General Hospital
Ashington
United Kingdom
NE63 9JJ

Sponsor information

Organisation

Northumbria Healthcare NHS Foundation Trust (UK)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Johnson & Johnson Medical Ltd. (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	01/03/2018		Yes	No
Protocol article	protocol	14/07/2014		Yes	No