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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

Registration date
27/03/2013

Overall study status
Completed

Last Edited
04/10/2018

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 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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-
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary outcome measures
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.

Overall study start date
01/05/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2600

Key exclusion criteria

Patients under 18

Date of first enrolment
01/05/2008

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wansbeck General Hospital
Ashington
United Kingdom
NE63 9JJ

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust (UK)

Sponsor details
Research and Development
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Industry

Funder Name
Johnson & Johnson Medical Ltd. (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	14/07/2014		Yes	No
Results article	results	01/03/2018		Yes	No