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A randomised controlled trial of triclosan coated sutures in primary total hip and total knee arthroplasty

Submission date
25/07/2013

Recruitment status
No longer recruiting

Registration date
20/08/2013

Overall study status
Completed

Last Edited
30/07/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Although safer than ever, infections after hip and knee replacements remain a challenging problem. Managing such infections often requires a long course of treatment and can lead to unhappy patients with poor function of the joint. Researchers are always looking for ways to prevent infection, as it has been proven that prevention, rather than treatment, provides the best outcome for patients. The aim of this study is to find out whether sutures (stitches) coated with an antiseptic agent called triclosan are able to reduce infections within a surgical wound, in people having total hip and total knee replacements. Triclosan is not a new drug and has been used for more than 30 years in toothpaste, cosmetics and antiseptic soaps. Triclosan-coated sutures have been successfully used to reduce infections after heart surgery, abdominal surgery and neurosurgery. It is hoped that the use of triclosan-coated sutures will work in a similar way when used in total hip and total knee replacements.

Who can participate?
Patients aged 18 or over undergoing primary hip or knee replacements in the Department of Trauma and Orthopaedics at University College London Hospital

What does the study involve?
The patients are randomly allocated to one of two groups. One group of participants receives triclosan-coated sutures during surgery and a second group receives an ordinary suture without triclosan. Neither the patient nor the investigator know which group the patient will be in. At the end of the operation the deep layers of the wound are stitched using either the triclosan-coated suture or the ordinary suture. The outside skin is closed as normal, using clips for both groups. This is the only difference between the two groups. The patient then receives our standard postoperative treatment for people undergoing total hip or total knee replacements. There is an extra clinic for the patient to attend at the hospital 2 weeks after the operation for inspection of the wound and removal of the skin clips rather than having that done at the GP surgery. Additionally, at the time of discharge the patient is given a simple yes/no questionnaire regarding their wound, which they are asked to complete and return in a pre-paid envelope two months after the operation.

What are the possible benefits and risks of participating?
It is not known for certain if triclosan-coated sutures will improve the wound healing or reduce infection rates in total hip and total knee replacements. However, there is a chance that these sutures will improve recovery time and joint function for hip and knee replacements. There may not be any benefit to you directly if you are placed in the group which will receive an ordinary suture without triclosan. Minimal inflammation of the surrounding tissues, localised irritation when skin sutures are left in place for greater than 7 days (sutures used in this study will only be used to close the deep layers of the wound), and slower absorption (>70 days) in tissues with poor blood supply as well as allergic reactions in the form of a rash or contact dermatitis have been reported with the use of triclosan. One study showed that triclosan-coated sutures increased the risk of wound separation in breast surgery. However, this was not supported by findings from other studies. Whilst rarely serious, the occurrence of any side effects will be sought while the patient is in hospital and at each subsequent hospital visit. The patient will be asked about hospitalisations, consultations with other medical practitioners and appropriate treatment will be provided according to the underlying problem.

Where is the study run from?
University College London Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2013 to August 2015

Who is funding the study?
University College London (UK)

Who is the main contact?
Prof. Fares Haddad

Contact information

Type(s)
Scientific

Contact name
Prof Fares Haddad

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University College London Hospital
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol version 8

Study information

Scientific Title
A randomised controlled trial of Polyglactin 910 Triclosan coated sutures versus standard Polyglactin 910 sutures in patients undergoing primary unilateral hip and knee arthroplasty

Study objectives
The hypothesis is that triclosan coated sutures may be associated with better wound healing characteristics and fewer infections than standard sutures, and as a result may potentially be more appropriate for total hip and total knee arthroplasty wound closures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES) Committee London - Harrow, 03/06/2013

Study design
Single-centred double-blind 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Primary total hip and knee replacement patients

Interventions
Participants will be randomly assigned to receive coated polyglactin 910 sutures with triclosan (Vicryl Plus; Ethicon, Inc.) or conventional sutures (coated polyglactin 910 ¨C Vicryl; Ethicon, Inc.).

Intervention Type
Procedure/Surgery

Phase

Not Applicable

Primary outcome measure
Healing characteristics, using the ASEPSIS wound scoring method devised in 1986 by Wilson et al at University College London Hospitals

Secondary outcome measures
Secondary objectives include recording data pertaining to demographics, procedure type, length of operating time, plus patient factors believed to influence wound healing and infection risk. Complications associated with using both sutures and their influence on early discharge will also be noted, as this may result in improved patient outcomes, cost effectiveness and long term prosthesis survival.

Overall study start date
15/08/2013

Completion date
15/08/2015

Eligibility

Key inclusion criteria
Adult patients undergoing unilateral primary total hip or knee replacement

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
420

Total final enrolment
150

Key exclusion criteria
1. Undergoing unilateral primary total hip or knee replacement for trauma
2. Undergoing a revision procedure or with a previous incision in the operative field
3. History of tendency for keloid formation
4. Allergy to triclosan/vicryl
5. Bleeding tendency (e.g. haemophilia and platelet disorders) or on regular anticoagulation treatment (e.g. warfarin, treatment dose of low molecular weight heparin (LMWH) or conventional heparin)
6. Underlying malignancy and immunocompromised status
7. Dementia and mental illnesses preventing informed consent
8. Children (age <18 years)

Date of first enrolment
15/08/2013

Date of final enrolment
15/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospital
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London (UK)

Sponsor details
UCLH/UCL Biomedical Research Unit
1st Floor, Maple House
149 Tottenham Court Road
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
University/education

Funder Name
University College London (UK)

Alternative Name(s)
University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
05/05/2019

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	18/07/2019		Yes	No