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Reducing implant infection in orthopaedics (RIIiO) pilot study

Submission date
20/02/2017

Recruitment status
No longer recruiting

Registration date
27/02/2017

Overall study status
Completed

Last Edited
09/09/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
A hip fracture is where there is a break in the upper thigh bone (femur). They are more common in older people as they are more likely to have weakened, brittle bones (osteoporosis) and tend to result from a fall. In most cases, surgery is the only treatment option for hip fractures. There are currently about 70,000 operations to repair hip fractures per year in the UK. In around 2.5% of these procedures, patients develop serious infections in the surgical cut (deep post-operative surgical site infection). This can lead to the need for further surgery, problems with recovery and long-term treatment with antibiotics. The risk of developing a surgical site infection (SSI) is reduced by preventing the body from becoming too cold (hypothermia) during surgery. The aim of this study is to find out whether the system used to keep patients warm during surgery influences the number who go on to develop SSI.

Who can participate?
Adults aged 60 and over who have a hip fracture and are scheduled to have a hip replacement surgery.

What does the study involve?
Participants are randomly allocated to one of two groups. All patients receive surgery as normal, but with a different warming system used during the procedure. Those in the first group receive Resistive Fabric Warming (RFW) during their surgery, which works like a low voltage electric blanket. This involves using a series of plastic coated, individually computer-controlled heating pads to warm the skin. Those in the second group receive Forced Air Warming (FAW) during their surgery. This involves using an electrical heater and a fan to blow warm air through a hollow paper duvet placed over the patient. There are holes in the duvet for the warm air to come out and heat the patient like a hair dryer. This is the usual method of warming used by hospitals. Participants in both groups are contacted one and three months after their surgery to assess their wellbeing. In addition, medical records are reviewed by the research team to find out how many in each group develop SSIs and how serious any infections are.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating, as the systems used in this study are currently being used in NHS hospitals and are equally good at keeping patients warm during surgery.

Where is the study run from?
1. Princess Royal Hospital, Haywards Heath (UK)
2. Horton General Hospital, Banbury (UK)
3. Wansbeck General Hospital, Ashington (UK)
4. Milton Keynes University Hospital (UK)
5. Sheffield Teaching Hospitals NHS Foundation Trust (UK)
6. East Kent Hospitals University NHS Foundation Trust (UK)
7. Heart of England NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2016 to March 2019

Who is funding the study?
Healthcare Infection Society, 3M and Nuffield Benefaction for Medicine and the Wellcome Institutional Strategic Support Fund (ISSF) at Oxford University (UK)

Who is the main contact?
Dr Matthew Scarborough
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Contact information

Type(s)
Public

Contact name
Dr Matthew Scarborough

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32470

Study information

Scientific Title
Pilot Study for a trial comparing the influence of forced air versus resistive fabric warming technologies on post-operative infection rates following orthopaedic implant surgery in adults

Acronym
RIIiO

Study objectives
The aim of this study is to investigate whether the risk of post-operative orthopaedic implant infection is influenced by the choice of intraoperative warming technology.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Coventry & Warwickshire Research Ethics Committee, 02/11/2016, ref: 16/WM/0451

Study design
Randomised; Interventional; Design type: Process of Care, Management of Care, Surgery

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
Specialty: Infectious diseases and microbiology, Primary sub-specialty: Infection prevention; UKCRC code/ Disease: Infection/ Bacterial, viral and other infectious agents, Injuries and Accidents/ Injuries to the hip and thigh

Interventions

Participants are randomised to one of two groups in a 1:1 ratio using an online system (MACRO).

Resistive Fabric Warming (RFW) group: Participants receive Resistive Fabric Warming (RFW) during their surgery. RFW works like a low voltage electric blanket. A series of plastic coated, individually computer-controlled heating pads are used to warm the skin by direct contact. The pads can be placed both under the patient and over the parts of the body away from the operating site.

Forced Air Warming (FAW) group: Participants receive Forced Air Warming (FAW) during their surgery. FAW uses an electrical heater and a fan to blow warm air through a hollow paper duvet placed over the patient. There are holes in the duvet for the warm air to come out and heat the patient like a hair dryer. At the moment, most hospitals use this system.

Participants will be followed up for 90 days from the date of surgery by telephone contact and review of medical notes.

Intervention Type
Other

Primary outcome measure
1. Recruitment rate is recorded as the number of eligible participantswho consent to participate in the study within 90 days of surgery.
2. Definitive deep surgical site infection (SSI) rate is measured through clinical observations within 90 days of surgery

Secondary outcome measures
1. Superficial surgical site infection (SSI) rate is measured through clinical observations within 90 days of surgery
2. Inadvertent perioperative hypothermia (IPH) rate is assessed using temperature measurements during surgery
3. Health Economic assessment is assessed using length of hospital stay, patient reported outcome measures for quality of life score (EQ-5D-5L), resource utilisation and serious adverse events (SAEs) including death within 90 days of surgery

Overall study start date
29/01/2016

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Provision of informed consent OR consultee declaration
2. Aged 60 years or over
3. Presenting with fracture of the hip
4. Scheduled to undergo hemiarthroplasty

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 700; UK Sample Size: 700

Total final enrolment
515

Key exclusion criteria
1. Previous surgery or infection of the affected hip
2. Hip fractures related to polytrauma
3. Patients managed without hemiarthroplasty
4. Receiving an investigational medicinal product related to infection

Date of first enrolment
01/04/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Princess Royal Hospital
Brighton and Sussex University Hospitals NHS Trust,
Lewes Road
Haywards Heath
United Kingdom
RH16 4EX

Study participating centre
Horton General Hospital
Oxford University Hospitals Foundation NHS Trust,
Oxford Road
Banbury
United Kingdom
OX16 9AL

Study participating centre
Wansbeck General Hospital
Northumbria Healthcare NHS Trust,
Woodhorn Lane
Ashington
United Kingdom
NE63 9JJ

Study participating centre
Milton Keynes University Hospital
Standing Way
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital site
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Based at: Queen Elizabeth the Queen Mother Hospital
St Peters Road
Margate
United Kingdom
CT9 4AN

Study participating centre
Heart of England NHS Foundation Trust
Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
Brighton and Sussex University Hospitals NHS Trust

Sponsor details
Royal Sussex County Hosptial
Eastern Road
Brighton
England
United Kingdom
BN2 5BE
+44 1273 696955
Scott.Harfield@bsuh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.bsuh.nhs.uk/

Funder(s)

Funder type
Research organisation

Funder Name
Healthcare Infection Society

Alternative Name(s)
The Healthcare Infection Society (HIS), Healthcare Infection Society (HIS), HIS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
3M

Alternative Name(s)
3M Company, 3M Science Applied to Life, 3M Science. Applied to Life. 3M United States, Minnesota Mining and Manufacturing Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Nuffield Benefaction for Medicine

Funder Name
Wellcome Institutional Strategic Support Fund (ISSF) at Oxford University

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal and at scientific conferences in 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
As this trial is designed as an pilot study, the investigators will not have unrestricted access to the raw data. If the pilot leads on to a definitive trial, data sharing may be possible dependent on contractual obligations.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/11/2018		Yes	No
Results article	results	01/12/2019	09/09/2019	Yes	No
HRA research summary			28/06/2023	No	No