

Reducing implant infection in orthopaedics (RIiO) pilot study

Submission date 20/02/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/09/2019	Condition category Infections and Infestations	<input type="checkbox"/> 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
Matthew.Scarborough@ouh.nhs.uk

Contact information

Type(s)

Public

Contact name

Dr Matthew Scarborough

Contact details

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Additional identifiers

Protocol serial number

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

RlliO

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

Study type(s)

Treatment

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(s)

1. Recruitment rate is recorded as the number of eligible participants who 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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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

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

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?
Results article	results	01/12/2019	09/09/2019	Yes	No
Protocol article	protocol	19/11/2018		Yes	No
HRA research summary			28/06/2023	No	No