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Comparison of skin disinfection procedures before surgery to determine if surgical wound contamination by skin bacteria can be reduced.

Submission date
22/01/2015

Recruitment status
No longer recruiting

Registration date
19/02/2015

Overall study status
Completed

Last Edited
07/02/2019

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims

An earlier study of spinal surgery, which we carried out at Queen's University Belfast (UK) and Musgrave Park Hospital Belfast (UK), showed that nearly 30% of surgery wounds contained bacteria from the patient's own skin, despite application of the antiseptic povidone iodine to the patient's skin before the operation. These patients did not have bad (acute) wound infections after surgery despite these bacteria getting into the surgery site. This means that the antibiotics that are normally injected into a patient's bloodstream during the operation to prevent infection (prophylaxis) worked. Bacteria are unfortunately becoming increasingly resistant to antibiotics. A well known example is methicillin-resistant Staphylococcus aureus (MRSA). If we do not take action now, this rise in antibiotic resistance will inevitably result in an increase in bacterial infection after surgery. We need to carry out research to improve how we prevent infection now. We therefore propose to see if we can improve on current procedures to kill bacteria on patient' s skin (skin antisepsis) before surgery, so that fewer bacteria get into surgical wounds (wound contamination) during an operation. Also, skin bacteria that might enter the body during surgery can grow on implanted materials, such as spinal implants, artificial joints, heart valves, breast implants, central nervous system shunts, permanent pacemakers, and nails and screws used to hold broken bones together while they heal. This can happen even when antibiotics are injected into the bloodstream during the surgery. These slow-to-develop, low-level (chronic) infections can lead to pain, loosening and eventual failure of the implanted device. It can in some cases take months or years after the operation for this to happen. The result is often another operation to replace the device. Improving skin antisepsis before surgery could therefore prevent failure of these implanted devices caused by bacteria growing slowly on the devices inside the body. Chlorhexidine gluconate and povidone iodine are skin disinfection antiseptics currently used separately that kill bacteria in different ways. Previously, there have been no studies to determine if chlorhexidine gluconate used in addition to povidone iodine reduces wound contamination in surgery. We therefore propose to determine if first applying the antiseptic povidone iodine to a patient's skin followed by application of the antiseptic chlorhexidine gluconate is better at reducing the number of bacteria that get into a surgical wound than applying povidone iodine twice. We will count how many bacteria are alive in samples from the surgery site. Bacteria that grow will be identified using DNA-based methods.

We will therefore be able to see if by using both antiseptics (chlorhexidine gluconate and povidone iodine) it will be possible to improve the contamination of surgical wound sites by skin bacteria. If this can be improved, there will be less chance of infection after the operation as fewer bacteria will be getting into the surgical wound. This will be important as more bacteria become resistant in the future to the antibiotics injected into the blood stream during a surgical operation. We are therefore trying to see if we can prevent a rise in postoperative infection, before too many bacteria become antibiotic resistant. An analogy might be that we are trying to shut the stable door before the horse has bolted, not after! Also implanted medical devices, such as artificial hips, heart valves and spinal implants, will be less likely to fail because of bacteria from the skin getting into the surgical wound and growing on the implant inside the body. This study is different to many other studies that involve patients because we are not investigating an effect on the patients themselves or their medical conditions. We are looking at the effect of the treatments on the bacteria on the patient's skin.

Who can participate?
The participants in the study will be adults who for various medical reasons have decided to have spinal surgery (elective surgery) within the Belfast Health and Social Care Trust Northern Ireland (UK), either at Musgrave Park Hospital (UK) or the Royal Victoria Hospital (UK). The study does not relate to the type of surgery, the clinical condition or the reason for the surgical treatment of the patient.

What does the study involve?
Patients will be randomly assigned to one of two groups. Patients' skin will be treated with either the skin antiseptic povidone iodine twice or one treatment with povidone iodine followed by one with the antiseptic chlorhexidine gluconate. A swab of the skin surface before antiseptic treatment, small samples of skin and muscle tissue and a saline wash of the surgical wound will be analysed to see if these samples contain living bacteria. The types of bacteria that grow from these samples will be determined by analysing the DNA of the bacteria.

What are the possible benefits and risks of participating?
It is unlikely that this study will have any major benefit to participants at this time.
There will be no more distress or inconvenience than that which participants would normally get because of the operation itself and there are no risks.

Where is the study run from?
Queen's University of Belfast (UK) and Belfast Health and Social Care Trust Northern Ireland (UK)

When is the study starting and how long is it expected to run for?
From November 2007 to June 2014

Who is funding the study?
1. Research and Development, Health and Social Care, Public Health Agency Northern Ireland (UK)
2. CareFusion Corporation
3. Mitre Trust Charity Northern Ireland (UK)

Who is the main contact?
Professor Sheila Patrick

Contact information

Type(s)
Scientific

Contact name
Dr Sheila Patrick

Contact details
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Additional identifiers

EudraCT/CTIS number
2009-016566-82

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Sponsor 05/SP/120, funder RRG9.41-RRG/3241/2005

Study information

Scientific Title
Skin bacteria as a source of surgical infections: molecular epidemiology and prevention of wound contamination. A randomised controlled trial to compare povidone iodine alone and povidone iodine plus chlorhexidine gluconate as skin disinfection for spinal surgery

Study objectives
1. Povidone iodine and chlorhexidine gluconate are skin disinfectants with different ways of killing bacteria
2. To determine if the sequential treatment of patients' skin with povidone iodine and chlorhexidine gluconate, just before surgical operation, will reduce surgical wound contamination by skin bacteria in patients undergoing spinal surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Health and Social Care Research Ethics Committee 3 (Northern Ireland), 22/12/2009, 09/NIR03/79
2. Medicines and Healthcare Products Regulatory Agency (MHRA) UK Clinical Trial of an Investigational Medicinal Product approval, 29/12/2009, ref CTA 32485/0015/001-0001

Study design
Randomised controlled single-centre interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Spinal surgical site wound contamination by bacteria and the implications for post-surgical infection

Interventions
Patients will be randomly assigned to one of two presurgical skin disinfection protocols:
1. Disinfection with povidone iodine (Videne Alcoholic Tincture) twice
2. Disinfection with povidone iodine (Videne Alcoholic Tincture) once, followed by treatment with chlorhexadine gluconate (Chloraprep).

The patient's skin will be swabbed before application of the skin disinfectant and bacterial growth under aerobic and anaerobic conditions determined. After skin disinfection and standard surgical incision, a small section of skin from the surgical wound edge and a separate piece of muscle tissue from within the wound will be removed, sterile saline will be poured into the base of the surgical wound, allowed to collect and then removed with a syringe. Samples will be processed for bacterial growth as soon as possible on receipt in the laboratory.

The study is open-label for the patients, surgeons and research nurses but blind for laboratory staff processing samples for bacterial culture.

Intervention Type
Procedure/Surgery

Primary outcome measure
Aerobic and anaerobic bacterial growth in each of the tissue samples.
Outcomes relate to the bacteria cultured from the samples obtained at the time of surgery and the subsequent analyses of these bacteria. No outcomes relating to patients.

Secondary outcome measures
1. To determine if the bacteria cultured from the surgical wounds are the same or different from bacteria on the patient's skin

2. Pure cultures of bacteria will be archived and identified subsequently using polymerase chain reaction DNA amplification and DNA sequence analyses
3. Antimicrobial resistance genes will also be examined

Overall study start date
01/11/2007

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Undergoing spinal surgery
2. Aged 18 and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. More than 7 days of hospitalisation before surgery
2. Transferred from another hospital
3. Overt spinal infections suspected preoperatively or evidence of purulence in any part of the wound during surgery
4. Sensitivity to the skin antiseptics
5. On antibiotics before surgery, other than surgical prophylaxis, because antibiotics can be excreted in sweat and could therefore affect the normal resident skin bacteria
6. Patients aged less than 18 years old
7. Pregnant women

Date of first enrolment
23/05/2010

Date of final enrolment
07/07/2014

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Queen's University Belfast
United Kingdom
BT7 1NN

Study participating centre
Belfast Health and Social Care Trust Northern Ireland
United Kingdom
BT9 7AB

Sponsor information

Organisation
Queen’s University Belfast

Sponsor details
University Road
Belfast
Northern Ireland
United Kingdom
BT7 1NN

Sponsor type
University/education

Website
http://www.qub.ac.uk/

Organisation
Belfast Health and Social Care Trust

Sponsor details
Research Office
2nd Floor King Edward Building
Royal Hospital
Grosvenor Road
Belfast

Northern Ireland
United Kingdom
BT12 6BA

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net/index.htm

Organisation
Queen's University Belfast

Sponsor details

Sponsor type
Not defined

Website
http://www.qub.ac.uk/

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
Research and Development, Health and Social Care, Public Health Agency Northern Ireland (UK)

Funder Name
CareFusion Corporation

Funder Name
Mitre Trust Charity Northern Ireland

Results and Publications

Publication and dissemination plan
Once the molecular analyses of the bacteria isolated the study has been completed we intend to publish the statistical analyses of the trial and molecular identification of the bacteria.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017		Yes	No
HRA research summary			28/06/2023	No	No