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LASER: assisted staphylococcal eradication

Submission date
29/05/2015

Recruitment status
No longer recruiting

Registration date
19/10/2015

Overall study status
Completed

Last Edited
27/06/2017

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Infections are a serious complication of major surgery, especially when this involves implantation of artificial devices such as knee or hip joints. Orthopaedic surgery is one of the most common types of surgery in which artificial devices such as joint replacements are used. A common type of infection is from a bacterium called Staphylococcus aureus (S. aureus). A resistant sub-type of this bacteria type is MRSA, which is well known to cause major problems because it is resistant to many antibiotics. About 30% of healthy people have S. aureus in their nose, and sometimes on other parts of their body. Some infections occurring after surgery may result from bacteria on a patients' own body spreading, and there is evidence that S. aureus spreading from sites such as the nose are important. At present, if MRSA is detected on a patient before they undergo surgery an eradication treatment regimen is routinely used, but this is not the case for other forms of S. aureus. It is quite difficult to effectively eradicate these bacteria before surgery, and the treatments required are quite inconvenient to patients. They involve applying ointment to the nose for 5 days, washing the body with antiseptics, gargling with an antiseptic mouthwash and changing bedsheets. A new treatment currently being investigated for the eradication of S. aureus in patients prior to surgery is one which uses a LASER. The treatment focuses a LASER on the area in the nose where S. aureus is typically found, and results suggest that it can increase the effectiveness of current eradication treatments. The LASER works by increasing the susceptibility of the bacteria to the existing treatments, making them more effective. The results of completed studies suggest the treatment is effective and safe, but large studies have not yet been carried out. The aim of this study is to see how efficient the current standard treatment is for patients prior to undergoing orthopaedic surgery, which doesn't use the LASER. This study also aims to test the protocol that would be used for enrolling patients, treating them, and taking the samples needed in a trial of the LASER therapy. This study will not use the LASER. The results of this study will be used in future studies which will evaluate how effective the LASER is when added to the treatments currently used in NHS hospitals to treat S. aureus in the nose before surgery.

Who can participate?
Adults scheduled for elective implant surgery that are found to be colonised with S. aureus.

What does the study involve?
All participants colonised with S. aureus are given the current eradication treatment currently recommended in national guidelines. Participants are asked to carry out a 5-day home treatment

regimen which includes using a nasal ointment, gargle mouthwash and a soap/shampoo substitute before they have orthopaedic implant surgery.

What are the possible benefits and risks of participating?
There may be potential benefits as patients on the study are screened and treated for MRSA and MSSA, current policy in NHS Scotland is to screen and treat for MRSA only. There is some evidence that eradicating MSSA in addition to MRSA prior to surgery reduces the risk of infection before surgery. There are no perceived risks for patients participating in this study.

Where is the study run from?
Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
June 2015 to November 2016

Who is funding the study?
Selex ES

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol version 3.2, 14 August 2015

Study information

Scientific Title
Laser Assisted Staphylococcal ERadication prior to elective orthopaedic implantation surgery (LASER study): pilot study phase I

Acronym
LASER

Study objectives
This is a feasibility study. The trialists want to measure how common Staphylococcus aureus (S. aureus) colonisation is in patients undergoing orthopaedic surgery and how efficient the current treatment is for S. aureus eradication. The trialists also want to test the protocol they would use for enrolling patients, treating them, and taking the samples needed in a future trial involving LASER therapy as an adjunct to clearing S aureus colonisation prior to surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee South East Scotland REC 02, 12/06/2015, ref: 15/SS/0091.

Study design
Prospective single-centre non-blinded feasibility study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Prevention

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
Orthopaedic patients presenting for elective implant surgery that are colonised with S. aureus

Interventions
All participants colonised with S. aureus will receive the decolonisation regimen currently recommended and used for MRSA eradication in NHS Lothian and recommended in national guidelines. A pack will be provided that includes day-by-day instructions for a 5-day treatment. This comprises:
1. Nose: Mupirocin 2% nasal ointment applied to the inner surface of each nostril (anterior nares) three times daily for 5 days. The participant should be able to taste mupirocin at the back of the throat after application.
2. Throat: Gargle mouthwash and oral hygiene with chlorhexidine gluconate 0.2% mouthwash solution twice daily for 5 days.
3. Body: Chlorhexidine gluconate 4% (Hibiscrub) solution as soap/shampoo substitute once daily for 5 days. Chlorhexidine solution must be kept in contact with the skin for at least 30 seconds and should be used as a shampoo at least twice in the 5 day period. An emollient and/or hair conditioner may be used if skin drying occurs. The skin should be moistened and the antiseptic

solution applied thoroughly to all parts of the skin before rinsing in a bath or shower. Do not dilute in bath water as the concentration would be insufficient. A disposable sponge or flannel should be used to apply the antiseptic solution.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Mupirocin, chlorhexidine

Primary outcome measure
Current primary outcome measures as of 05/06/2017:
Proportion of participants cleared of nasal SA at 48-96 hours after completing current eradication regimens for S. aureus

Previous primary outcome measures:
Proportion of participants positive for nasal S. aureus 48-96 hours post eradication regimen as determined by microbial analysis

Secondary outcome measures
Current secondary outcome measures as of 05/06/2017:
Feasibility outcomes
1. Consent rates as proportion of eligible participants
2. Recruitment rates
3. Protocol compliance rates

Clinical outcomes
1. Clearance rates of SA from all 3 sampled sites at 48-96 hours after completing current eradication regimens for MRSA.
2. Clearance rates of SA from all 3 sampled sites at hospital admission (pre-surgery) after completing current eradication regimens for MRSA.
3. Clearance rates of SA from all 3 sampled sites at hospital discharge (post-surgery) after completing current eradication regimens for MRSA.
4. Clearance rates of SA from all 3 sampled sites at 6 weeks follow-up after surgery after completing current eradication regimens for MRSA.
5. Adverse event and serious adverse event rates reported in phase I and II of pilot

Previous secondary outcome measures:
Feasibility outcomes:
1. Consent rates as proportion of eligible patients
2. Recruitment rates
3. Protocol compliance rates

Clinical outcomes:
1. Clearance rates of S. aureus from all 3 sampled sites at 48-96 hours after completing current eradication regimens
2. Clearance rates of S. aureus from all 3 sampled sites at hospital admission (pre-surgery) after completing current eradication regimens

3. Clearance rates of S. aureus from all 3 sampled sites at hospital discharge (post-surgery) after completing current eradication regimens
4. Clearance rates of S. aureus from all 3 sampled sites at 6 weeks follow-up after surgery after completing current eradication regimens
5. Adverse event and serious adverse event rates
6. Rate of HAIs at 6 weeks post-surgery
7. Hospital length of stay; 6 week follow-up measures
8. Rates of mupirocin resistance at baseline
9. Rates of biofilm forming S. aureus at baseline

Overall study start date
01/06/2015

Completion date
30/11/2016

Eligibility

Key inclusion criteria
1. Patient is scheduled for elective implant surgery
2. Patient is attending pre-operative assessment clinic within 8-21 days of planned surgery
3. Patient has confirmed nasal colonisation with S. aureus (MSSA or MRSA) after pre-operative assessment using a rapid PCR test for MRSA and MSSA

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
50-100

Key exclusion criteria
1. Patient with allergy or other contraindication to mupirocin or chlorhexidine treatment
2. Patient known to have mupirocin or chlorhexidine resistant SA
3. Patient unable to wait the 3-4 hours for the SA screening result
4. Patients in whom microbiological treatment for SA other than decolonisation is planned prior to hospital admission for surgery
5. Patients receiving antibiotics in the last 2 weeks or planned to receive antibiotics prior to surgery (excluding routine peri-operative antibiotic prophylaxis)
6. Patient scheduled to receive joint revision surgery due to infection
7. Patient lives too far from the hospital to be followed-up for microbiological sampling
8. Patient aged <16 years
9. Pregnancy or breastfeeding
10. No informed consent

Date of first enrolment
20/10/2015

Date of final enrolment
20/04/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Royal Infirmary of Edinburgh
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University of Edinburgh

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Sponsor type
University/education

Website
http://www.accord.ed.ac.uk

Organisation

NHS Lothian

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Sponsor type
Hospital/treatment centre

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http://www.nhslothian.scot.nhs.uk

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University of Edinburgh

Sponsor details

Sponsor type
Not defined

Website
http://www.ed.ac.uk/home

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Industry

Funder Name
Selex ES

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/11/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. T Walsh (timothy.walsh@ed.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		05/06/2017	26/06/2017	No	No
HRA research summary			28/06/2023	No	No