ISRCTN13950775 https://doi.org/10.1186/ISRCTN13950775

A tool to predict the risk of surgical wound infection enabling infection prevention strategies in heart surgery

Submission date
28/10/2021

Recruitment status
No longer recruiting

Registration date
04/03/2022

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims:
Surgical site infections (SSIs) are commonly associated with heart surgery patients. Statistics indicate that wound infection is linked to increased death rates and other health complications. Also, this is expensive for healthcare systems as they are stretched to provide care for patients with complex wound infections. Therefore, this study aims to explore how wound infections can be prevented, and what difficulties healthcare staff might be having in monitoring infections in patients.

Who can participate?
Patients aged 18-85 years old who are having coronary bypass graft surgery (CABG), specifically those who have been invited for surgery. Participants who are admitted on an urgent basis will also be considered to take part in this study. However, participants who have been admitted as an emergency case will be excluded from the study as It's not possible to monitor their pre-surgical journey.

What does the study involve?
There are three parts to this study; firstly, the researcher will look at the current evidence to see what the risk factors are for wound infections amongst heart surgery patients. In the second part of the study, they will watch some operations and follow the patient through their journey to see what it's like for them. Following on from this, patients will be interviewed once they are discharged home to get their views on how wound infections can be prevented. Also, hospital staff will be interviewed to get an understanding of their views too. The third part of the study involves an audit of 29 heart surgery centres in England to see what the practice is like nationally. Staff and service users will complete a survey. Interviews will also be carried out with 16 staff and 4 service users to understand the difficulties they may face in caring for wound infections and monitoring them.

What are the possible benefits and risks of participating?
The study is low risk, and in the event of a potential concern that may arise during the observations or interviews then the researcher will contact the safeguarding lead at the

participating site. The benefit of participating in the study is that health professionals and clinicians can identify the most effective wound infection preventive strategies in heart surgery patients which can help to improve patients' overall health and quality of life.

Where is the study run from?
The University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
January 2021 to June 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Prof. Gavin Murphy, gjm19@hotmail.com
2. Prof. Judith Tanner judith.tanner@nottingham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
295054

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 50656, IRAS 295054

Study information

Scientific Title
A surgical site infection risk prediction tool to enable targeted infection prevention strategies in adult cardiac surgery

Acronym
Target SSI

Study objectives
WP 1: What are the risk factors that predict wound infection in adult patients having cardiac surgery?
WP 2: What is usual care for patients undergoing cardiac surgery?
What are the barriers and facilitators to implementing interventions to prevent wound infections?
WP 3: What are the barriers and facilitators to accurate wound infection surveillance?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/11/2021, East of Scotland REC 1 (East of Scotland Research Ethics Service, Tayside Academic Health Sciences Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital& Medical School, Dundee, DD1 9SY, United Kingdom; +44 (0)1382 383871; tay.eosres@nhs.scot), ref: 21/ES/0098

Study design
Observational; Design type: Qualitative

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Adult cardiac surgery

Interventions
This is a qualitative study involving observations and interviews.

32 patients across four cardiac centres in England will be observed by the study researchers. The observation period for each patient will not exceed 1 day. Patients will be observed as they progress from the admission ward to the theatre and to the surgical ward. Observations will focus on the interventions given to the patient that prevent wound infections.

The 32 observed patients will be given an opportunity to take part in an interview after they have been discharged home. Four patients will be interviewed. The interviews will take place online and last 30-60 min. The focus of the interviews is potential patient contribution to interventions to prevent wound infection.

The researchers will interview 20 staff across the four cardiac centres. The interviews will take place online and last 30-60 min. The focus of the interviews is compliance with interventions to prevent wound infection.

The researchers will invite surveillance/infection prevention leads at all 29 cardiac centres in England to complete an audit describing their wound infection surveillance practices for cardiac surgery.

The researchers will distribute a staff surveillance survey and a service user surveillance survey. The surveys are online and will take 20 min to complete. The focus is barriers and facilitators to compliance with surveillance and how patients and carers can get involved with surveillance. They will be distributed via the study web page (hosted by the University of Leicester) and also sent out via the Cardiac Interdisciplinary Research Network, the National Cardiac Benchmarking Collaboration and infection prevention leads and cardia surgery leads at all 29 cardiac centres in England.

The researchers will interview 16 staff about compliance with wound infection monitoring and reporting. The interviews will take place online and last 30-60 min. The researchers will recruit participants through the surveillance survey.

The researchers will interview four service users about compliance with wound infection monitoring and reporting. The interviews will take place online and last 30-60 min. The researchers will recruit participants through the surveillance survey.

Intervention Type
Other

Primary outcome(s)
1. Process map of the cardiac surgical patient journey, measured in month 6 using data from patient observations in months 1, 2 and 3
2. Barriers and facilitators to the implementation of interventions to prevent wound infections, measured by staff and patient interviews during months 2, 3 and 4 of WP 2

3. Barriers and facilitators to the implementation of wound infection surveillance. measured by staff and Patient and Public Involvement (PPI) survey in month 1 of WP 3 and also by staff and PPI interviews in months 1 and 2 of WP 3

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Patients for observations:
Patients are eligible if they:
1. Are having CABG surgery at a participating site during the study observation period
2. Are an elective or an urgent surgery patient
3. Are able to give informed consent
4. Are between 18 and 85 years
5. Have, or do not have, an existing infection
6. Have, or do not have, an existing condition or disability
7. Are any gender, ethnicity or socioeconomic group
8. Able to speak English (or have translator/interpreter available)

Patients for intervention interviews:
Patients are eligible if they:
1. Took part in the patient observations component of the study
2. Have been discharged from hospital
3. Have access to online interview facilities

Staff for interventions interviews:
Staff are eligible if they:
1. Work at a participating site
2. Contribute to the cardiac surgical patient journey
3. Represent a professional group identified through the observations
4. Have access to online interview facilities
5. Are any gender, ethnicity or age range

Surveillance audit:
Staff are eligible if they:
1. Are the surveillance lead or infection prevention lead at a cardiac centre in England

Staff surveillance survey:
Staff are eligible if they:
1. Are the surveillance lead or infection prevention lead at a cardiac centre in England, or
2. Contribute to the cardiac surgical patient journey, or
3. Contribute to cardiac surveillance programme

Service user surveillance survey:
Any service user is eligible to take part, whether they have had surgery or not, or whether they care for someone who has had surgery or not, any gender or ethnicity

Staff for wound monitoring interviews:
Staff are eligible if they:
1. Took part in the surveillance survey and volunteered to take part in an interview
2. Work in a cardiac centre
3. Have access to online interview facilities
4. Are any gender, ethnicity or age range

Service users for wound monitoring interviews:
Service users are eligible if they:
1. Took part in the surveillance survey and volunteered to take part in an interview
2. Have been a surgical patient (any specialty), have been a carer for a surgical patient, are a member of the public
3. Have had, or have not had a surgical wound infection
4. Have access to online interview facilities
5. Can give informed consent
6. Are between 18 and 85 years
7. Are any gender, ethnicity or socioeconomic group

Participant type(s)
Patient, Health professional, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
85 years

Sex
All

Key exclusion criteria
Patients for observations:
Patients are not eligible if they:
1. Are not having CABG surgery at a participating site during the study observation period
2. Are having emergency surgery
3. Are not able to give consent
4. Are younger than 18 years or older than 85 years

Patients for intervention interviews:
Patients are not eligible if they:
1. Did not take part in the patient observations component of the study
2. Do not have access to online interview facilities
3. Have not been discharged from hospital

Staff for interventions interviews:
Staff are not eligible if they:
1. Do not work at a participating site
2. Do not contribute to the cardiac surgical patient journey
3. Do not have access to online interview facilities
4. Do not represent a professional group identified through the observations

WP 3 Surveillance audit:
Staff are not eligible if they:
1. Are not the surveillance lead or infection prevention lead at a cardiac centre in England

WP 3 Staff surveillance survey:
Staff are not eligible if they:
1. Are not the surveillance lead or infection prevention lead at a cardiac centre in England, or
2. Do not contribute to the cardiac surgical patient journey, or
3. Do not contribute to the cardiac surveillance programme

Surveillance audit:
Staff are not eligible if they:
1. Are not the surveillance lead or infection prevention lead at a cardiac centre in England

Staff surveillance survey:
Staff are not eligible if they:
1. Are not the surveillance lead or infection prevention lead at a cardiac centre in England, or
2. Do not contribute to the cardiac surgical patient journey, or
3. Do not contribute to the cardiac surveillance programme

Staff for wound monitoring interviews:
Staff are not eligible if they:
1. Did not take part in the surveillance survey and did not offer to take part in an interview
2. Do not work in a cardiac centre
3. Do not have access to online interview facilities

Service users for wound monitoring interviews:
Service users are not eligible if they:
1. Did not take part in the surveillance survey and did not offer to take part in an interview
2. Do not have access to online interview facilities
3. Are unable to give consent
4. Are younger than 18 years or older than 85 years

Date of first enrolment
01/01/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
Liverpool Heart and Chest Hospital
Thomas Drive
Liverpool
United Kingdom
L14 3PE

Study participating centre
Harefield Hospital
Hill End Road
Harefield
Uxbridge
United Kingdom
UB9 6JH

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
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BS1 3NU

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202620

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2023	07/12/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		25/01/2025	28/01/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes