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Exploring if patients can safely and easily swab their own surgical wounds at home

Submission date
26/09/2025

Recruitment status
Recruiting

Registration date
06/10/2025

Overall study status
Ongoing

Last Edited
06/01/2026

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
After surgery, almost one in ten patients develops a problem with their wound at home, such as an infection or a reopening. These problems can lead to wounds taking longer to heal, patients being readmitted to hospital, further surgery, increased costs for the NHS and reduced patient quality of life. Ideally, a problem wound should be swabbed to see if any or which bacteria are present and causing the infection. This helps inform the treatment or choice of antibiotic given. However, difficulties in being seen in person at the GP practice mean that wounds are not always swabbed, and some patients receive delayed or the wrong antibiotic treatment. This delay can make the wound problem worse, further delay the healing and add to the problem of antibiotic resistance, where antibiotics no longer work. This study aims to find out whether patients can safely and acceptably self-swab their surgical wounds at home. It will assess the usability of the swabs and explore whether self-swabbing could be cost-effectively integrated into existing clinical pathways.

Who can participate?
Adults aged 18 or over who have had cardiac surgery resulting in a closed central chest wound may take part. This includes patients undergoing either elective or urgent surgery. Participants may be living at home or in a care home following discharge.

What does the study involve?
To join the study, individuals must be able to give written informed consent and be able to take part in the study procedures. Patients who have had cardiac surgery will be invited to take part in the study before or after their operation. Those who agree will be given a swab kit to take home when they are discharged. Within three weeks of leaving the hospital, they will be asked to swab their wound themselves, while being supported and observed remotely by a research practitioner. The swabs will be sent to an independent NHS laboratory for testing. Participants will also take part in a short interview about their experience using the kit. A follow-up check will take place around 30 days after surgery to monitor wound healing and any signs of infection.

What are the possible benefits and risks of participating?
Participants may not receive direct care benefits. This study will help improve the approach to wound care and management. Implementing home swabbing for surgical wounds could

significantly improve timely access to correct treatments, reducing unnecessary antibiotic use. The overall risk of taking part in this study is low. There are small risks related to doing the swab at home, such as uncertainty with the swabbing process or feeling upset or distressed. These will be managed by providing clear step-by-step instructions, video support with a research practitioner, and following the study's distress protocol. Only patients whose wounds are confirmed as closed by the research practitioner will be invited to take part. Follow-up has been kept to a minimum to reduce any burden on participants. Any patient data that is analysed by people outside the direct clinical team will be de-identified to protect confidentiality

Where is the study run from?
This study is a collaboration of researchers and surgeons across the country. It is co-ordinated by the Sponsor, Guys and St Thomas' NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
April 2025 to May 2026 (overall study start and completion)
January 2026 to February 2026 (recruitment and follow-up period)

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

Who is the main contact?
Ms Melissa Rochon, Chief Investigator, melissa.rochon1@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
356847

ClinicalTrials.gov (NCT)
NCT07200401

Central Portfolio Management System (CPMS)
70181

National Institute for Health and Care Research (NIHR)
207935

Study information

Scientific Title
A feasibiliTy study to exploRE the safety, Acceptability and potential cost effectiveness of Self-swabbing at home to obtain usable surgical wound cultURE swabs (TREASURE)

Acronym
TREASURE

Study objectives
PRIMARY OBJECTIVE
. To determine the feasibility, safety, and acceptability of patients self-swabbing their surgical wounds at home to obtain usable culture swabs that can detect clinically significant organisms.

SECONDARY OBJECTIVES
•To evaluate the outputs of a previous co-production focus group (instructions and kit) for usability, clarity, and acceptability as part of the feasibility study.
•To evaluate patient and carer satisfaction with the swabbing instructions and kit (designed through the previous co-production focus group) through observations and interviews.
•To assess whether the swab samples collected by patients at home are viable for laboratory analysis and arrive at the lab within a specified timeframe (24 hours).
•To identify any barriers to patient participation, such as perceived difficulties or concerns during self-swabbing.
•To explore and prioritise the most appropriate and cost-effective pathway for implementing self-swabbing in the NHS.
•To conduct a preliminary health economic analysis to identify potential costs, benefits, and savings associated with home-based self-swabbing, including resource usage and antibiotic prescribing patterns.
•To generate recruitment, adherence, and outcome data that will inform the design of a larger substantive clinical trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/08/2025, West of Scotland REC 4 (Research Ethics – Room 29, 2nd Floor, Administration Building, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; -; Ggc.WoSREC4@nhs.scot), ref: 25/WS/0079

Study design
Mixed-methods non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Complications of surgical and medical care, not elsewhere classified, to assess whether patients can self-swab surgical wounds at home

Interventions
This mixed-methods feasibility study aims to assess whether patients can self-swab surgical wounds at home. A feasibility design was chosen to assess the acceptability, usability, and logistical feasibility of home-based self-swabbing for surgical site infection (SSI) detection following cardiac surgery, before a larger trial. PPI input has shaped all patient-facing materials and procedures, and members of the PPI group believe the proposed process is acceptable and understandable.

The study incorporates two main components: a clinical feasibility study involving patient participants and stakeholder interviews.

The clinical feasibility study will be conducted at two sites: Harefield Hospital and the Royal Sussex County Hospital. A total of 40 patients who have undergone cardiac surgery will be recruited during their inpatient stay - 25 from Harefield and 15 from the Royal Sussex County Hospital.

Potential participants will be identified by the usual care team through surgical admissions lists. Verbal consent will be sought from patients who express an interest in taking part, to share their contact details with a member of the research team, which will be documented in the medical notes and on the screening log.

Before admission to the hospital, around one week before the patient comes in for surgery, a delegated member of the study team will discuss the study with these patients over the telephone. Patients who express an interest in the study will be able to discuss the study in more detail, be provided the opportunity to ask questions, and be sent written information about the study. Patients will be sent written information about the study. Patients will be given a minimum of 24 hours to consider participation in the study.

During their inpatient stay, before discharge, informed consent will be obtained by a delegated member of the research team. Upon enrolment, a delegated member of the research team will collect demographic and operational details from the medical notes.

At discharge, recruited participants will also be given a swab kit, a swab label and a return label by the research practitioner. The swabbing observation date will be agreed upon between the patient and the research practitioner. If the research practitioner is unavailable at the time, the swab kit and labels will be sent to the patient, and the video observation date will be arranged via a telephone call within 7 days of discharge.

Between 1 and 21 days post-discharge, a video observation of the self-swabbing procedure will be conducted. This will take place via MS Teams in the participant's chosen location (e.g. their home) and will be facilitated by a delegated member of the research team. During the session,

the research team member will review any adverse events and confirm that the wound still meets the study's inclusion criteria. Guided by the instructions provided in the kit and under observation, the participant will perform the wound swab. Once completed, the swab will be placed in a pre-addressed, sealed envelope and arranged for collection within 24 hours. Post-swabbing interview date will also be arranged within 14 days of the video-observed session.

The swab kit will be collected from the participant's nominated location and brought to an external lab within the UK for processing and reporting. The research practitioner will confirm and record the date and time of swab arrival at the lab, along with the swab result.

Within 14 days of video observation, the research practitioner based at Harefield Hospital will conduct a follow-up video call with each participant. During this call, any adverse events will be reviewed, and a delegated member of the research team will carry out a brief interview to explore the participant's views on the acceptability and experience of self-swabbing.

At 30 days post-surgery (+/- 7 Days), participants will receive a routine follow-up to monitor for any signs of surgical site infection (SSI):

Wound Check: The usual care team will collect wound information using a standard questionnaire, either online or by phone for those without digital access.

GP Contact: If a participant reports taking antibiotics for a wound infection, the research practitioner will contact their GP by phone or email to confirm the details.

Medical Record Review: At Harefield Hospital, the research team will review medical notes to check for wound-related readmissions. The team is also exploring remote access to Brighton's records for the same purpose.

Adverse Event Monitoring: Any complications will be recorded during this period. All participants will continue receiving standard post-op care, including GP advice, hospital visits, or being asked to report any concerns.

Between months 7-9, ten qualitative stakeholder interviews will be conducted. The usual care team and the research team will approach potential participants using convenience sampling until each professional group is represented. The usual care team will identify one representative from each of the following groups: specialist nurses, surgeons, laboratory staff and microbiologists employed by Harefield Hospital or the Royal Sussex County Hospital. The research team will identify a GP, a commercial company that makes patient at-home tests and a commissioner.

Potential staff stakeholder participants will be given a leaflet about the study and asked to contact the study research team if they are interested in taking part. The study research practitioner will phone the interested staff member, providing information and answering any questions.

Stakeholder interview participants will be given a minimum of 24 hours to consider their participation in the study. Consent will be provided over email or verbally before commencing the interview. The interviews will take place at a time agreed with each participant.

Intervention Type
Other

Primary outcome(s)

Current primary outcomes as of 02/01/2026:
1. Feasibility of home-based wound self-swabbing, defined as the proportion of patients completing the procedure successfully (i.e. compliance with swabbing instructions) with samples received at the laboratory within 24 hours, and deemed suitable for processing.
2. Number of participants who adhere to the swabbing protocol. Evaluated during observations conducted at the time of swabbing and during follow-up interviews
3. Adverse events during the swabbing process were evaluated during observations conducted at the time of swabbing and during follow-up interviews
4. Acceptability of the swabbing process, assessed through Likert scale ratings and qualitative interviews immediately after wound swabbing observation

Previous primary outcomes:
The feasibility of home-based patient self-swabbing of surgical wounds will be assessed by the proportion of participants who successfully perform self-swabbing at home approximately 2 weeks post-discharge, with the swab sample delivered to the laboratory within 24 hours and deemed viable for laboratory analysis.

Key secondary outcome(s))

Current secondary outcomes as of 02/01/2026:
1. Acceptability of the swabbing kit will be measured using Likert scales (quantitative) and thematic analysis from participant interviews (qualitative), measured during participant interviews immediately after wound swabbing observation
2. Acceptability of the swabbing instructions will be measured using Likert scales (quantitative) and thematic analysis from participant interviews (qualitative), measured during participant interviews immediately after wound swabbing observation
3. Transport Time taken for swabs to reach the laboratory, measured in hours, collected during laboratory processing
4. Number of usable swabs (viable for analysis), measured during laboratory processing
5. Recruitment and retention rates, to be measured continuously during the trial to inform the design of a larger trial
6. Patient demographics distribution to be measured continuously during the trial to inform the design of a larger trial
7. New swabbing at home pathway, generated from stakeholder interviews and cost-effectiveness work

Previous secondary outcomes:
1. Acceptability of the swabbing process will be measured using Likert scales (quantitative) and thematic analysis from participant interviews (qualitative), measured during participant interviews immediately after wound swabbing observation
2. Acceptability of the swabbing process will be measured using Likert scales (quantitative) and thematic analysis from participant interviews (qualitative), measured during participant interviews immediately after wound swabbing observation
3. Acceptability of the swabbing process will be measured using Likert scales (quantitative) and thematic analysis from participant interviews (qualitative), measured during participant interviews immediately after wound swabbing observation
4. Number of participants who adhere to the swabbing protocol. Evaluated during observations conducted at the time of swabbing and during follow-up interviews
5. Adverse events during the swabbing process were evaluated during observations conducted at the time of swabbing and during follow-up interviews
6. Transport Time taken for swabs to reach the laboratory, measured in hours, collected during

laboratory processing
7. Number of usable swabs (viable for analysis), measured during laboratory processing
8. Recruitment and retention rates, to be measured continuously during the trial to inform the design of a larger trial
9. Patient demographics distribution to be measured continuously during the trial to inform the design of a larger trial

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Cardiac surgery ≥18 years old patients with a central chest wound, where the wound is closed, assessed by the research practitioner
2. Patients having elective or urgent surgery
3. Patients who have been discharged home or to a care home
4. Willing and able to provide written informed consent before participation in the clinical investigation
5. Willing and able to comply with all study-related procedures, with or without digital resource /internet access

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Cardiac surgery patients with open wounds extending beyond skin level, or where deep tissue, organs or implants are visible, wounds with constant or heavy discharge of fluid, or wounds leaking pus at the time of the video consultation
2. Patients having emergency or salvage surgery
3. Patients still in hospital
4. Patients with a dressing covering their wound at the time of the video consultation.

5. Congenital or acquired immunodeficiency, bone marrow disease, diabetes, autoimmune conditions requiring immunosuppressive treatment, or any immunosuppressive medication at the time of consent or within the last 4 weeks before consent
6. Undergoing active cancer treatment at the time of consent/ or planning to start cancer treatment within the study period, or having completed cancer treatment within the last 4 weeks of the study commencing
7. Patients who lack the capacity to consent

Date of first enrolment
06/01/2026

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
England
SE1 7EH

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
England
BN2 5BE

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes