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Using artificial intelligence within digital wound monitoring of surgical wounds to prioritise non-healing wounds for urgent review

Submission date
09/01/2024

Recruitment status
No longer recruiting

Registration date
15/03/2024

Overall study status
Ongoing

Last Edited
02/12/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims

Over 10 million surgical operations are performed in England annually with approximately 2.1 million having problems with wound healing, of which 500,000 lead to infection. Most of these wound problems happen after patients have been discharged from the hospital. They need to be identified and treated early to prevent the problem from worsening.

Digital remote surgical wound monitoring is beginning to be used to monitor patients' surgical wounds at home after discharge from the hospital. This offers regular assessment when wound problems are most likely to develop. Early evaluations of digital wound monitoring suggest it improves clinical outcomes and has high patient satisfaction; however, it creates a new additional workload for clinicians.

Who can participate?

Patients ≥18 years old having first/redo coronary artery bypass graft (CABG) surgeries with or without adjunct cardiac procedures such as valve replacement, or chest reopening during same admission as index surgery, and either no infection, or an existing non-infected wound complication, or any other infection except surgical site, at any of two recruitment sites (St Bartholomew's Hospital, London and Freeman Hospital, Newcastle). Patients without a smartphone/with physical disability/with visual impairment will be eligible if they are willing to use a smartphone or internet provided by the study, or their next of kin or carer is able-bodied or has a smartphone.

What does the study involve?

The study will assess a new component for a digital wound monitoring platform, which has been developed and has recently received HRA approval to be validated for predictivity, sensitivity and specificity, and inter-rater reliability. The new component uses artificial intelligence (AI) to identify 'red flags' on the images patients submit to the wound monitoring platform. Images that have a possible red flag are then identified for urgent priority review. This helps clinicians manage this new workload by allowing the most urgent cases to be reviewed first.

A total of 120 patients in two hospitals will be invited to take part in the study. All participants (patients who take part) will receive normal wound care follow-up after surgery, and half of the

participants will also receive the digital wound monitoring system with the AI to identify wounds which need urgent assessment.

What are the possible benefits and risks of participating?
Participants allocated to the digital wound monitoring with AI may benefit from regular and ongoing wound assessment. Participants allocated to standard wound care may not receive additional direct benefits. This study will help improve the approach to Wound care.
There are no foreseeable disadvantages involved with taking part since all participants will receive their usual standard wound care follow-up. Being involved will require participants to give some of their own time.

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

When is the study starting and how long is it expected to run for?
December 2023 to March 2025

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

Who is the main contact?
Melissa Rochon, Melissa.Rochon@gstt.nhs.uk

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)
338141

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 338141, NIHR204508, CPMS 60580

Study information

Scientific Title
Wound Imaging Software and Digital platfOrM to detect and prioritise non-healing surgical wounds (WISDOM)

Acronym
WISDOM

Study objectives
Can we successfully develop artificial intelligence to prioritise images of patients' surgical wounds that are failing to heal or are infected, in order to facilitate early treatment?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/02/2024, North of Scotland Research Ethics Committee 1 (Aberdeen Royal Infirmary, Foresterhill Road, Aberdeen, AB25 2ZN, United Kingdom; +44 1224558458; gram.nosres@nhs.scot), ref: 24/NS/0005

Study design
Two-centre interventional unblinded parallel-group randomized feasibility study

Primary study design

Interventional

Study type(s)
Prevention, Quality of life, Safety

Health condition(s) or problem(s) studied
Investigation of an artificial intelligence module to prioritise review of non-healing cardiac surgical wounds in adults

Interventions
This project is a two-centre, unblinded parallel-group randomised feasibility study with safety and acceptability outcomes comparing the wound prioritisation module with standard care. A total of 120 patients from St Bartholomew's Hospital London and The Freeman Hospital Newcastle will be recruited to the trial over a ten-month period. The London site provides a wider range in ethnicity and a city location while the Newcastle site includes patients from rural locations. We will recruit 60 patients to each of the two groups (to include around 45 from Barts and 15 from The Freeman for each group).

Potential participants will be identified by delegated member of the usual care team through surgical admissions lists. Final eligibility for study enrolment will be assessed after surgery, prior to discharge or up until day five after surgery – whichever comes first.

Randomisation will be implemented in the electronic data capture system by Derby CTSU. The sequence generation will be based on a random seed, selected by the study Statistician, who will have no prior knowledge of the allocation sequence until after generation. Participants will be assigned to the intervention or control group, using stratified 1:1 randomisation with mixed block sizes to maximise the chances of equal allocation to groups. Participants will be allocated a treatment arm in the eCRF (via a Randomisation form), where allocation details will be stored online and an email notification sent to the study team. Access to the online randomisation system will be via personal username and password, and specific to role.

Participants will not be blinded as to their group allocation. This is because of obvious differences between the intervention and standard care. The hospital staff who are delivering wound care will be aware of the patient's allocation status.

Control Group: Patients in the control group will have standard post-operative wound care follow-up for 60 days.
Standard care, mapped during the economic scoping exercise may include; out-patient appointments, advised to contact GP, or no follow-up.

Intervention Group: The intervention group will use the artificial intelligence enabled platform with the new wound prioritisation module for 30 days after surgery in addition to standard post-operative wound follow-up care for 60 days after surgery. Patients in the intervention group will be contacted via SMS text message seven days, fourteen days and twenty-one days after surgery with the link request remining open for 6 days until the next request is sent out. The exception being the last request link which will remain open until 30 days after surgery. In the requests patients are asked to submit a photo of their wound and complete the UKHSA wound surveillance questionnaire. Participants can also submit an image during the 30 days whenever they have a concern.

Data Collection:
We will develop online surveys for patients and staff focusing on safety, acceptability, and barriers to underserved groups. Interviews with staff/patients exploring issues raised in surveys. Purposive sampling to include a range of ages, sex, ethnicities, physical abilities/carer dependence and socioeconomic status. Other tools include platform review, medical notes review and patient telephone calls at 30 and 60 days.
30 days has been chosen as the data collection point as this is the recommended follow-up time for a wound infection as stipulated by the national wound surveillance programme run by the UKHSA. Further data is collected at 60 days to identify any adverse events such as hospital re-admissions or further surgery the patients may have had.

At baseline we will collect the following data:
• SF 6Dv2 (added 25/07/2024)

After 30 days we will collect the following data:
• online satisfaction survey with participants in both groups (15 minutes each), hosted on Dacima
• online satisfaction survey with staff (15 minutes each), hosted on Dacima
• online interviews (focusing on satisfaction and experience) with a subsection of 10 patients from both groups – 20 in total, lasting around 40 minutes, conducted via Microsoft Teams
• online interviews (focusing on satisfaction and experience) with a subsection of 10 staff, lasting around 40 minutes, conducted via Microsoft Teams
• Wound prioritisation module platform review for intervention group only to see number of wound images correctly prioritised (i.e. no disparity between clinician and Isla flags)
• Phone call to all patients to discuss their wound and any treatments or healthcare interventions / engagement they may have had (15 minutes each)
• SF 6Dv2 (added 25/07/2024)

After 60 days we will collect the following data:
• Medical case note review for all patients to identify re-admissions or further surgery
• Patient phone call to discuss their wound and any treatments or healthcare interventions / engagement they may have had (15 minutes each)
• SF 6Dv2 (added 25/07/2024)

Intervention Type
Other

Primary outcome(s)
1. Safety outcomes: quality of images received, assessed by clinicians at 30 days. A quality image is one that can be used to make a clinical decision.
2. Acceptability outcomes: clinician and patient satisfaction using surveys and interviews at day 30. Acceptability of the intervention including attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy. Will also collect acceptability of being involved as a study participant.
3. Feasibility outcomes: recruitment rate, adherence with the module (intervention group only), loss to follow-up. Adherence will be reported as the number and percentage of adherent patients in the intervention group. To be adherent a patient needs to submit 1 photo within the 30 day period. This will be compared with the progression criteria defined in the protocol. The definitive study will proceed (or not) based on these outcomes.
4. Economic modelling outcomes: Will include number and severity of wound problems

/infections, wound-related hospital readmission, prescribed antibiotics time to review images, further surgery to treat wounds, prescribed wound treatments, clinic visits, GP visits, patient travel time, and quality of life SF 6Dv2 (added 25/07/2024)

Key secondary outcome(s))
1. Safety outcomes. More detailed discussion about reasons for compliance/non-compliance will be explored in the staff surveys and interviews and the patient intervention group surveys and interviews. Survey data will be analysed using descriptive statistics and qualitative data from the interviews will analysed using thematic analysis.
2. Feasibility outcomes: access/barriers to participation and willingness of participants to be randomised, and attrition rates and suitability of assessment procedures and outcome measures, including time and resources required to conduct telephone assessments to patients and phone calls to GPs to collect antibiotic data. To contribute to sample sizes for a definitive trial - number and severity of wound problems/infections, wound-related hospital readmission, further surgery to treat wounds, prescribed wound treatments, prescribed antibiotics, clinic visits, GP visits.
3. Other secondary outcomes: number of photos received (per patient), number of requests (for images) complied with -intervention group only, number photos initiated by patients (intervention group only), number of follow-up requests.

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Patients having first/redo CABG surgeries with or without adjunct cardiac procedures such as valve replacement, or chest reopening during same admission as index surgery, and either no infection, or an existing non-infected wound complication, or any other infection except surgical site.
2. Patients without a smartphone/with physical disability/with visual impairment will be eligible if they are willing to use a smartphone or internet provided by the study, or their next of kin or carer is able-bodied or has a smartphone.

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex

All

Total final enrolment
121

Key exclusion criteria
1. Patients having CABG requiring ventricular assist device (VAD) or
2. Extracorporeal membrane oxygenation (ECMO), or
3. Ventilated or unconscious patients, or
4. Pre-existing surgical site infection

Date of first enrolment
15/08/2024

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

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
On completion of the study, anonymised quantitative data from the surveys, interviews and phone calls and anonymised themed analysis of qualitative data from the interviews will be stored in and made publicly available through the University of Nottingham data repository (https://rdmc.nottingham.ac.uk/).

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/09/2024	26/09/2024	Yes	No
Participant information sheet	Participant information sheet version 2.0	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.2	31/01/2024	15/03/2024	No	No

Protocol file	Study website	19/03/2025	29/04/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes