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Exploring if artificial intelligence can be used to help monitor patients after surgery

Submission date	Recruitment status	[X] Prospectively registered
15/10/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/10/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2024	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The surgical repair of complex wounds sometimes requires the movement of tissue from one area of the body to another. The new tissue is “plumbed” into the new location by joining the blood vessels under a microscope. This type of surgery is called microvascular free flap surgery and whilst overall success rates are very good there can be problems in the first three days that require intervention in theatre. If these problems are identified early there is a greater chance of salvage and hence, doctors and nurses conduct frequent checks of the patients and the flap after the operation. These routine post-operative checks include measuring the patient’s observations (e.g. heart rate and blood pressure), assessing the flaps' colour and temperature and using a Doppler ultrasound machine to hear the blood flow to the flap. This study investigates if a computer model, trained on images of free flaps and routine free flap monitoring data, can detect problems with free flaps earlier and more accurately than human assessment.

Who can participate?
Adult patients aged over 16 years old undergoing microvascular free flap surgery at either of the participating hospitals (St Johns Hospital, Livingston or the Royal Victoria Infirmary, Newcastle) will be invited to take part in the study.

What does the study involve?
For patients who choose to participate in the study, their microvascular free flap surgery will go ahead as normal, but in addition to the normal checks after the operation, photographs will also be taken of the flap at least twice a day. Once patients have completed the normal observation period and been discharged home, their flap photographs and monitoring data will be anonymised and collected for the study. A computer program will then be used to analyse the flap photographs and patient data. As this analysis is done after the patient has completed their treatment and been discharged home, it will not impact their care. The knowledge gained from analysing study participant's data will be used to make a tool that could help monitor other patients’ free flaps after surgery.

What are the possible benefits and risks of participating?
There will be no direct benefits for patients who participate in the study but by allowing us to

use their data we can hopefully build a model that could be used in the future to improve monitoring after free flap surgery for other patients.

There is a small risk for patients included in the study that when we take photographs of their flap there could be things in the background that could be used to identify them. To reduce this risk all photographs are cropped so that only the flap is in the image. Furthermore, taking photographs in clinical settings is very carefully regulated and all regulations will be followed to make sure patient photographs are protected.

Where is the study run from?
This study has been organised by Miss Fiona Smith, a medical doctor who is currently studying for a PhD degree in Biomedical Artificial Intelligence at the University of Edinburgh. This study is sponsored by the University of Edinburgh and NHS Lothian. Data collection takes place at participating hospitals (St Johns Hospital, Livingston or the Royal Victoria Infirmary, Newcastle) and then the anonymous data is uploaded by the local research team to a secure server called "REDCap" which will allow the research team members located at the University of Edinburgh to access the anonymous data and analyse it.

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

Who is funding the study?
UK Research and Innovation (UKRI) Centre for Doctoral Training in Biomedical AI at the University of Edinburgh, School of Informatics.

Who is the main contact?
The main contact is the Principal Investigator, Miss Fiona Smith (fiona.smith32@nhs.net)

Study website
https://www.anastomosis-study.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
325880

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 63913, UK Research and Innovation grant: EP/S02431X/1

Study information

Scientific Title
Artificial intelligence approaches to monitoring surgical inpatients

Acronym
AnAsToMoSIs

Study objectives
Microvascular free flap surgery is a key technique utilised for the reconstruction of complex tissue deficits secondary to trauma and neoplasia. Free flap surgery involves the transfer of tissue (which can be any combination of skin and subcutaneous fat and/or muscle and/or bone), from one area of the body to another with its own blood supply. Whilst overall success rates are very good, this is only achieved by close postoperative monitoring to identify the complications that require immediate re-operation for correction.

This study investigates if computer models, trained on images of free flaps and routine free flap monitoring data, can detect problems with free flaps earlier and more accurately than human assessment.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 03/07/2024, West of Scotland Research Ethics Service REC 5 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 24/WS/0071

2. Approved 08/07/2024, HRA and Health and Care Research Wales (HCRW) (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; approvals@hra.nhs.uk), ref: 24/WS/0071

Study design
Multicentre prospective observational descriptive cohort study

Primary study design

Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Diagnostic

Participant information sheet
Participant information can be found at: https://www.anastomosis-study.com

Health condition(s) or problem(s) studied
Microvascular free flap failure

Interventions
Patients undergoing elective and trauma microvascular free flap reconstructive surgery at participating NHS hospitals will be invited to join the study. In addition to receiving the current gold standard of care (routine checks by staff where they measure the patients' observations and check the appearance, temperature and Doppler ultrasound signal from the flap) study participants will also have photographs of their free flaps taken and these and the data from the routine free flap checks will be collected and anonymised and sent to the University of Edinburgh for analysis.

AI models will be built to analyse each of the different types of data. For example, computer vision models will be trained on images of free flaps to see if the computer can detect subtle changes in flap appearance that could indicate a problem with the flap. The different AI models will then be combined to build a computer model that predicts the risk of free flap problems.

This study will result in a prognostic model that when given a new patient's free flap post-operative monitoring data, will predict if the free flaps are normal (i.e. no abnormalities detected) or abnormal (i.e. showing signs of developing a complication). As per the TRIPOD checklist, the performance measures for the prognostic model produced will be reported with confidence intervals.

Intervention Type
Procedure/Surgery

Primary outcome measure
The accuracy of the prognostic model (including precision, recall, AUC/ROC curve and F1 score) in predicting whether free flaps are normal or abnormal measured using patient data stored in “REDCap” of post-operative monitoring data, including routine checks and photographs, in patients undergoing elective and trauma microvascular free flap reconstructive surgery at participating NHS hospitals at one timepoint

Secondary outcome measures
Risk factors for free flap failure and for developing other complications, such as deep vein thrombosis and infection, measured using an analysis of patient data stored in “REDCap” of patients' demographic data and post-operative monitoring data at one timepoint

Overall study start date
01/01/2023

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. All adult plastic surgery patients (≥16 years old) undergoing reconstructive microvascular free flap surgery
2. Patient has the capacity to consent for inclusion in the study

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Children (<16 years old)
2. Patients who lack the capacity to consent for inclusion in the study

Date of first enrolment
21/10/2024

Date of final enrolment
26/07/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre

St Johns Hospital
Howden Road West,
Howden
Livingston
United Kingdom
EH54 6PP

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
The University of Edinburgh

Sponsor details
The Queen’s Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ
+44 (0)131 242 3325
resgov@accord.scot

Sponsor type
University/education

Website
https://www.accord.scot/

Organisation
NHS Lothian

Sponsor details
The Queen’s Medical Research Institute
47 Little France Crescent
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Sponsor type
Hospital/treatment centre

Website
https://www.accord.scot/

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal. The study will also be reported in Miss Fiona Smith's PhD thesis.

Intention to publish date
31/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be made available for ethically approved research on reasonable request from Miss Fiona Smith, who is the Principal Investigator for the study (fiona.smith32@nhs.net). Patients are made aware of this in the Patient Information Sheet and during the Informed Consent process.

IPD sharing plan summary

Available on request