

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 16/10/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 16/10/2024	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Miss Fiona Smith

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

## **Integrated Research Application System (IRAS)**

325880

### **Protocol serial number**

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**

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### **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

### **Study type(s)**

Diagnostic

### **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(s)

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

### Key secondary outcome(s)

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

### Completion date

31/07/2025

## Eligibility

### Key inclusion criteria

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

### Participant type(s)

Patient

### Healthy volunteers allowed

No

**Age group**

Mixed

**Lower age limit**

16 years

**Sex**

All

**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**

United Kingdom

England

Scotland

**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

## Organisation

NHS Lothian

# 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

## 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes