

# Imperial Prostate 8 - fluorescence confocal microscopy for rapid evaluation of surgical cancer excision

<b>Submission date</b> 01/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/10/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/10/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study aims to evaluate the use of a new imaging technique called fluorescence confocal microscopy (FCM) for real-time identification of positive surgical margins in prostate cancer surgery. Positive surgical margins (PSMs) occur when cancer cells are found at the edge of the removed tissue after surgery. Detecting PSMs accurately is important to ensure complete cancer removal during prostate cancer surgery.

### Who can participate?

Patients over the age of 18 years with prostate cancer undergoing radical prostatectomy (surgical removal of the prostate) at Imperial College Healthcare NHS Trust, University College London Hospitals NHS Foundation Trust, or Guy's & St Thomas' NHS Foundation Trust during the study period

### What does the study involve?

Participants scheduled for prostate cancer surgery will undergo the standard robotic-assisted surgical procedure. During the surgery, a new imaging technique called FCM will be used to scan the removed prostate tissue. FCM uses fluorescent dyes to enhance cell visibility, providing real-time high-resolution images of the tissue. These images will be compared to traditional histopathology (examination of tissue samples under a microscope) to determine the accuracy of FCM in detecting positive surgical margins.

### What are the possible benefits and risks of participating?

The potential benefits of participating in the study include contributing to the evaluation of a new imaging technique that could improve the accuracy of detecting positive surgical margins during prostate cancer surgery, leading to better cancer treatment outcomes. There are no specific risks associated with participating in the study, as it involves the use of an ex vivo (outside the body) imaging technique. Any risks associated with the surgical procedure itself will be managed according to the standard of care.

Where is the study run from?  
Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?  
November 2022 to August 2024

Who is funding the study?  
1. The Urology Foundation (TUF) (UK)  
2. The John Black Charitable Foundation (UK)

Who is the main contact?  
Mr Nikhil Mayor, n.mayor@imperial.ac.uk

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-way-to-assess-tissue-samples-taken-during-prostate-surgery-ip8-fluoresce>

## Contact information

**Type(s)**  
Principal investigator

**Contact name**  
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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

12275

## Study information

### Scientific Title

A multicentre blinded prospective cohort study to assess the accuracy of digital fluorescence confocal microscopy for assessment of surgical margins in radical prostatectomy specimens

### Acronym

IP8-FLUORESCENCE

### Study objectives

This study aims to evaluate whether digital fluorescence confocal microscopy can accurately detect positive surgical margins in patients undergoing radical prostatectomy for localised prostate cancer.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 10/05/2023, Wales REC3 (Health and Care Research Wales Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)29 2078 5741; Wales.REC3@wales.nhs.uk), ref: 22/WA/0214

### Study design

Multicentre ex-vivo single-centre blinded prospective cohort study

### Primary study design

Observational

### Study type(s)

Diagnostic, Efficacy

### Health condition(s) or problem(s) studied

Prostate cancer

### Interventions

Prostate specimens from subjects undergoing radical prostatectomy (RP) will be stained with a fluorescent dye (Histolog Dip) and then be scanned on a digital fluorescent confocal microscope (FCM) known as the Histolog Scanner. The specimens will then undergo conventional

histopathological analysis. A pathologist will undertake a blinded analysis to evaluate the accuracy of FCM for evaluation of surgical margins in prostate cancer.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Histolog® Scanner

**Primary outcome(s)**

Accuracy of digital FCM measured using the Histolog Scanner in detecting clinically significant prostate cancer at surgical margins at radical prostatectomy compared to traditional H&E histopathology (reference standard). Measures used to assess accuracy will be sensitivity, specificity, positive and negative predictive value. Clinically significant cancer is defined as Gleason score  $\geq 7$  (ISUP Grade Group  $\geq 2$ ).

**Key secondary outcome(s)**

1. Sensitivity, specificity, positive and negative predictive value of digital FCM for detection of cancer at surgical margins, with traditional H&E histopathology as the reference standard, on a per-image/margin level
2. Area under the receiver operating characteristic curve (AUC) for cancer detection of digital FCM with traditional H&E histopathology as the reference standard
3. Agreement of digital FCM with the pathology report for cancer length at margin (mm) on a margin and patient level
4. Agreement of digital FCM with the pathology report for cancer grade at margin (mm) on a margin and patient level
5. Cohen's kappa coefficient for agreement between readers (two individual histopathologists, histopathologist vs trainee histopathologist, histopathologist vs urologist)

**Completion date**

01/08/2024

**Eligibility****Key inclusion criteria**

1. Men aged  $\geq 18$  years
2. Men undergoing radical prostatectomy at Imperial College Healthcare NHS Trust during the study period
3. Nerve sparing and non-nerve sparing radical prostatectomy cases

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Male

**Total final enrolment**

156

**Key exclusion criteria**

Current exclusion criteria as of 09/05/2024:

1. Men who do not consent for ex vivo tissue research
2. Men who are listed for salvage prostatectomy and had a previous prostate cancer treatment (radiotherapy, brachytherapy, focal therapy)

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Previous exclusion criteria:

1. Men who do not consent for ex vivo tissue research through Imperial College Healthcare Tissue Bank (ICHTB)
2. Men who are listed for salvage prostatectomy and had a previous prostate cancer treatment (radiotherapy, brachytherapy, focal therapy)
3. Men enrolled in concurrent clinical trials requiring ex vivo prostatic tissue for research

**Date of first enrolment**

17/08/2023

**Date of final enrolment**

30/06/2024

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Charing Cross Hospital**

Fulham Palace Road

London

United Kingdom

W6 8RF

**Study participating centre**

**University College London Hospitals NHS Foundation Trust**  
250 Euston Road  
London  
United Kingdom  
NW1 2PG

**Study participating centre**

**Guy's and St Thomas' Hospitals**  
Trust Offices  
Guy's Hospital  
Great Maze Pond  
London  
United Kingdom  
SE1 9RT

## Sponsor information

**Organisation**

Imperial College Healthcare NHS Trust

**ROR**

<https://ror.org/056ffv270>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Urology Foundation

**Alternative Name(s)**

The Urology Foundation (TUF), TUF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Funder Name**

John Black Charitable Foundation

**Alternative Name(s)**

The John Black Charitable Foundation, JBCF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during the study will be available upon request from Nikhil Mayor (n.mayor@imperial.ac.uk)

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		10/10/2025	20/10/2025	Yes	No
<a href="#">Protocol file</a>	version 1.2	02/04/2024	09/05/2024	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes