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

Submission date 01/08/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 09/10/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/06/2024	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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

Study website
https://www.imperialprostate.org/clinical-trials

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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-FLUORESCE

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

Secondary study design
Cohort study

Study setting(s)
Hospital, Laboratory

Study type(s)
Diagnostic, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Histolog® Scanner

Primary outcome measure
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 defines as Gleason score >/= 7 (ISUP Grade Group >/=2).

Secondary outcome measures
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)

Overall study start date
30/11/2022

Completion date
01/08/2024

Eligibility

Key inclusion criteria
1. Men aged >/=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

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
155

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
England

United Kingdom

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

Sponsor details
Joint Research Office
AHSC Directorate Office
1st Floor, North Corridor
Hammersmith Hospital
London
England
United Kingdom
W12 0HS
+44 (0)20 3313 1000
donna.copeland@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.imperial.nhs.uk/

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Charity

Funder Name
Urology Foundation

Alternative Name(s)
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

Publication and dissemination plan
Results will be presented at national and international urological meetings in the UK and abroad. Planned publication in a peer-reviewed urological journal.

Intention to publish date
01/08/2025

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?
Protocol file	version 1.2	02/04/2024	09/05/2024	No	No