

Imperial Bladder 1 - Fluorescence COnfocal Microscopy for raPid evaluation of detrusor muscle at primary transurethraL rsEctTion of bladdEr tumours (IB1-LaserCOMPLETE)

Submission date 04/07/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/08/2024	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/11/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Bladder cancer is the seventh most commonly diagnosed cancer and it is 3 to 4 times more common in men than in women. Bladder cancer is first diagnosed by tissue obtained from a transurethral resection of bladder tumour (TURBT) operation. This involves passing a telescope into the bladder along the urethra (water pipe) and removing bladder tumours (growths) using diathermy (electrical current) or laser energy. In 7 in every 10 patients diagnosed with bladder cancer, the cancer is present in the “superficial” layer of the bladder and does not grow deeper into the bladder muscle layer. Treatments for this form of superficial cancer such as bladder installations of chemotherapy or immunotherapy have been effective in reducing the chance of the bladder cancer recurring or progressing over time. Therefore, a key determinant of the correct treatment allocation following this operation is whether muscle was obtained to allow a pathologist to report the correct depth of cancer invasion. Unfortunately, performing this operation can be challenging and in up to 30% of patients there will be no muscle present in the tissue obtained to make an accurate assessment. The knowledge of this will become available 1-2 weeks following the operation. In most patients, the treating urologist will ask for the operation to be repeated to obtain this muscle sample. This has a significant impact on patient's health, quality of life, and a large financial burden on our healthcare service. This study proposes the use of a novel scanner known as “fluorescence confocal microscopy” that could scan and report acquired bladder tissue in the operating theatre “live” to determine if a muscle is present, providing immediate feedback to the operating surgeon. This technology has been used in other urological cancers such as prostate cancer to determine if prostate cancer has spread beyond the gland at the time of prostate removal in real-time. However, it has never been used in this form of bladder cancer operation. If this study proves possible, a larger practice-changing study will be planned to compare this technology against traditional reporting.

Who can participate?

Adult patients undergoing initial or first TURBT for suspected bladder cancer

What does the study involve?

Bladder cancer specimens from subjects undergoing TURBT operation will be stained with a fluorescent dye (Histolog Dip) and scanned on a digital fluorescent confocal microscope (FCM) known as the Histolog Scanner. The specimens will then undergo conventional histopathological analysis. A pathologist will analyse the accuracy of FCM to evaluate detrusor status (presence or absence).

What are the possible benefits and risks of participating?

Patients will derive no direct benefits from taking part. There have been no reported risks from scanning ex vivo tissue using the Histolog scanner.

Where is the study run from?

When is the study starting and how long is it expected to run for?

February 2024 to July 2025

Who is funding the study?

1. The Urology Foundation (TUF) and Chris Howell Urological Research Award from the Penguins Against Cancer Charity (Dr M Connor) are providing funding to Imperial College Healthcare NHS Trust to cover the delivery of the trial excluding the cost of the Histolog scanner and Histolog related consumables.

2. SamanTree Medical SA is providing the Histolog scanner and Histolog-related consumables without any charge.

Who is the main contact?

Dr Martin Connor, m.connor@imperial.ac.uk

Principal Investigator, IB1-LASERComplete

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Martin Connor

ORCID ID

<https://orcid.org/0000-0003-4033-7508>

Contact details

Charing Cross Hospital, Imperial College Healthcare NHS Trust

London

United Kingdom

W6 8RF

+44 (0)20 3313 1000

m.connor@imperial.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

ICHTB HTA licence: 12275

Study information

Scientific Title

A prospective feasibility study to assess ex vivo real-time analysis of detrusor muscle status at time of primary transurethral resection of bladder tumour (TURBT) using fluorescence confocal microscopy

Acronym

IB1-LaserCOMPLETE

Study objectives

This study aims to determine the feasibility of using fluorescence confocal microscopy to identify the presence of detrusor muscle in primary transurethral resection of bladder tumour (TURBT) specimens.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 05/04/2024, Health Research Authority (HRA) - Wales Research Ethics Committee (REC) 3 (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

Prospective, feasibility design (ex vivo) study

Primary study design

Observational

Study type(s)

Diagnostic, Efficacy

Health condition(s) or problem(s) studied

Bladder cancer

Interventions

Bladder cancer specimens from subjects undergoing transurethral resection of bladder tumour (TURBT) operation 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 an analysis to evaluate the accuracy of FCM for the evaluation of detrusor status (presence or absence).

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Histolog® Scanner

Primary outcome(s)

The feasibility of using digital fluorescence confocal microscopy to identify the presence /absence of detrusor muscle in primary transurethral resection of bladder tumour (TURBT) specimens measured by a pathologist who will determine the accuracy at one timepoint

Key secondary outcome(s)

1. Establish a standard operating procedure for scanning fresh bladder tissue from primary TURBTs using the Histolog FCM machine at one timepoint
2. Agreement of digital FCM with the pathology report for detrusor presence on a specimen at a patient level. Sensitivity, specificity, positive and negative predictive value of digital FCM for detection of detrusor muscle with traditional H&E histopathology as the reference standard, on a per-patient basis at one timepoint
2. Agreement between readers measured by: a) two individual histopathologists; and, by b) a histopathologist versus an operating urological surgeon (Cohen's kappa coefficient) at one timepoint

Completion date

14/07/2025

Eligibility

Key inclusion criteria

Patients undergoing initial or first transurethral resection of bladder tumour (TURBT) for suspected bladder cancer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

35

Key exclusion criteria

1. Radiological or clinical suspicion of muscle-invasive bladder cancer (cT2-T4)
2. Prior diagnosis of NMIBC or MIBC on prior resection
3. Patients who do not consent for ex vivo tissue research through Imperial College Healthcare Tissue Bank (ICHTB)
4. Patients enrolled in concurrent clinical trials requiring ex vivo tissue for research

Date of first enrolment

15/07/2024

Date of final enrolment

15/01/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Charing Cross Hospital

Fulham Palace Road

London

England

W6 8RF

Sponsor information

Organisation

Imperial College Healthcare NHS Trust

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Imperial College London

Alternative Name(s)

Imperial College of Science, Technology and Medicine, Imperial College London, UK, Imperial College London, London, England, Imperial College London in United Kingdom, imperialcollege, ICL

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mr M Connor (m.connor@imperial.ac.uk). Information on the type of data that will be shared will be provided later. The timing for availability is 1 year following completion and/or peer-review publication of the study, whichever is earlier.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 1.0	11/08/2025	27/08/2025	No	No
Statistical Analysis Plan	version 2	03/11/2025	26/11/2025	No	No