ISRCTN16114765 https://doi.org/10.1186/ISRCTN16114765

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

Registration date
20/08/2024

Overall study status
Completed

Last Edited
22/10/2024

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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Dr Martin Connor

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital, University/medical school/dental school

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
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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
28/02/2024

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

Age group
Adult

Sex
Both

Target number of participants
35

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
England

United Kingdom

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Sponsor information

Organisation

Imperial College Healthcare NHS Trust

Sponsor details
Joint Research Office
AHSC Directorate Office
1st Floor
North Corridor
Hammersmith Hospital
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United Kingdom
W12 0HS
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Sponsor type
Hospital/treatment centre

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

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

Publication and dissemination plan
Peer-reviewed journals, national and international conferences

Intention to publish date
15/07/2025

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