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New methods of follow up on urinary bladder cancer

Submission date 02/07/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/08/2025	**Overall study status** Ongoing	
Last Edited 11/08/2025	**Condition category** Cancer	

Plain English summary of protocol
Background and study aims
The study aims to improve follow-up on patients diagnosed with urinary bladder cancer using endomicroscopy.

Who can participate?
Adult patients with diagnosed urinary bladder cancer stratified as pT1, who have to undergo re-endoresection of the urinary bladder tumor.

What does the study involve?
The study involves a cystoscopy under general anesthesia - examination of the urinary bladder via urethra and intravenous application of a fluorescent agent.

What are the possible benefits and risks of participating?
The benefit of the study is to improve future follow-up of patients with pT1 bladder cancer, during a procedure that will only prolong the necessary surgery for a few minutes.

The main risk of participating is an allergic reaction to the fluorescent agent.

Where is the study run from?
The research is a part of doctoral studies at the University Hospital Brno, Czech Republic

When is the study starting and how long is it expected to run for?
April 2024 to December 2027

Who is funding the study?
The University Hospital Brno, Czech Republic

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
PIG6/24

Study information

Scientific Title
New methods of follow-up on non-muscle invasive urinary bladder cancer using confocal laser endomicroscopy

Acronym
UBCLEM

Study objectives
The study is focused on patients with non-muscle invasive urinary bladder cancer. The group of patients with histology findings pT1 are recommended to undergo a second endoresection of the bladder tumor to prevent a recurrent disease and to exclude the presence of residual tumor. During the procedure, the bladder mucosa will be examined by a confocal laser endomicroscope. This will provide a real-time microscopic imaging of the mucosa that will be used to distinguish between benign and malignant lesions. The procedure will continue with standard endoscopic repeated resection of suspicious tissue to compare the results from confocal laser endomicroscopy with histopathological results. This study aims to find out whether confocal laser endomicroscopy is precise enough compared with histopathological examination. The secondary aim is to try to prevent patients from second re-endoresection if a procedure under general anesthesia is not inevitable.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/04/2024, Ethics Board of The University Hospital Brno (Jihlavská 20, Brno, 62500, Czech Republic; +420532232798; etickakomise@fnbrno.cz), ref: Reference number: 09-100424 /EK, Project number: 52/24

Primary study design

Interventional

Study design
Single-centre interventional controlled trial

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
Follow-up care and treatment of patients diagnosed with urinary bladder cancer.

Interventions
This interventional study includes patients with non-muscle invasive bladder cancer, stratified as pT1. The patients will undergo a standard second re-endoresection of the urinary bladder tumor. Before this procedure under general anesthesia, the mucosa of the bladder will be examined with laser confocal endomicroscopy. This examination will provide real-time visualisation of atypical mucosa and submucosa cells. A fluorescent agent is administered intravenously shortly before examination to aid visualisation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Malign and benign lesions during re-endoresection of urinary bladder tumor will be measured using laser confocal endomicroscopy at one time point

Key secondary outcome(s)
Confirmation between benign and malignant lesions will be undertaken after the examination by laser confocal endomicroscopy, using histopathological examination at one time point

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Patients with diagnosed urinary bladder cancer stratified as pT1, who have to undergo re-endoresection of the urinary bladder tumor.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Key exclusion criteria
First histological examination without detection of muscle tissue (pTX), incomplete first resections.

Date of first enrolment
01/09/2025

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Czech Republic

Study participating centre
University Hospital Brno
Jihlavská 20
Brno
Czech Republic
62500

Sponsor information

Organisation
University Hospital Brno

ROR
https://ror.org/00qq1fp34

Funder(s)

Funder type
University/education

Funder Name
University Hospital Brno

Funder Name
Masarykova Univerzita

Alternative Name(s)
Masaryk University, MU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan
Identifiable patient data will not be available or shared with a third party. The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request