

# New methods of follow up on urinary bladder cancer

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<b>Registration date</b> 11/08/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/08/2025	<b>Condition category</b> 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

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-endoresction 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?

Dr Mária Moravčíková, [moravcikova.maria@fnbrno.cz](mailto:moravcikova.maria@fnbrno.cz)

## Contact information

**Type(s)**

Public, Scientific, Principal Investigator

**Contact name**

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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**

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**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

**Study design**

Single-centre interventional controlled trial

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic, Treatment

**Participant information sheet**

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

**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-endoresction 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 measure**

Malign and benign lesions during re-endoresction of urinary bladder tumor will be measured using laser confocal endomicroscopy at one time point

**Secondary outcome measures**

Confirmation between benign and malignant lesions will be undertaken after the examination by laser confocal endomicroscopy, using histopathological examination at one time point

**Overall study start date**

01/04/2024

**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

**Age group**

Mixed

**Lower age limit**

18 Years

**Upper age limit**

100 Years

**Sex**

Both

**Target number of participants**

60

**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

## Sponsor details

Jihlavská 20

Brno

Czech Republic

62500

+420532233860

kralikova.iveta@fnbrno.cz

## Sponsor type

Hospital/treatment centre

## Website

<https://www.fnbrno.cz/urologicka-klinika/k1490>

## 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**

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

01/12/2028

**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