

# Prognostic value of molecular subtypes in bladder cancer

<b>Submission date</b> 07/01/2019	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2019	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/12/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims

During the last five years knowledge about molecular subtypes in bladder cancer has emerged. This means that bladder cancer is not one disease, but a heterogenous disease entity. The aim of this study is to investigate how molecular subtypes affect prognosis and progression-free survival in bladder cancer.

Who can participate?

Patients with bladder cancer who have undergone transurethral resection of the tumour (TURB)

What does the study involve?

Participants undergo molecular subtyping by means of RNA sequencing from tumour samples. They are followed up for at least two years to assess progression-free survival.

What are the possible benefits and risks of participating?

There are no risks of participating in this study neither are there any obvious benefits as the treatment will not be changed in this study according to the findings of the molecular subtyping.

Where is the study run from?

1. Malmö University Hospital
2. Landskrona Hospital
3. Helsingborg Hospital
4. Ängelholm Hospital
5. Central Hospital Kristianstad
6. Ljungby Hospital
7. Växjö Hospital
8. Blekinge Hospital
9. Ystad Hospital

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

January 2017 to June 2026

Who is funding the study?

1. Cancerfonden
2. BioCARE
3. Krapperup fond
4. ALF
5. MAS Cancer

Who is the main contact?

Prof. Fredrik Liedberg

## Contact information

### Type(s)

Scientific

### Contact name

Prof Fredrik Liedberg

### Contact details

Institution of Translational Medicine, Lund University

Section of Urology

Malmö University Hospital

Malmö

Sweden

221 05

## Additional identifiers

### Protocol serial number

01/2019

## Study information

### Scientific Title

Bladder cancer molecular subtypes in clinical practice (UROSCANSEQ)

### Acronym

UROSCANSEQ

### Study objectives

Application of molecular subtypes in clinical practice is necessary to gain knowledge about molecular classification.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Regionala Etikprövningsnämnden i Lund (the Regional Ethical Review Board in Lund), Box 133, 221 00 Lund, Tel: +46 (0)46 2224180, Email: [registrator@epn.lu.se](mailto:registrator@epn.lu.se), 10/03/2017, ref: 2012/74 and 2017/34

**Study design**

Multicentre prospective cohort-study.

**Primary study design**

Observational

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Urothelial carcinoma of the urinary bladder

**Interventions**

RNA-sequencing of bladder tumours and molecular subtyping and assessment of molecular grade. Patients will be followed up for at least two years after inclusion to assess progression-free survival.

**Intervention Type**

Genetic

**Primary outcome(s)**

Molecular subtype and grade. The timepoints for assessment of the primary and secondary outcomes will be standardised according to the Swedish national guidelines for bladder cancer regarding recommended follow-up intervals. For the study population this means control with cystoscopy every third month for two years, every sixth month the following three years and then annually with a lifelong follow up.

**Key secondary outcome(s)**

Progression-free survival. The timepoints for assessment of the primary and secondary outcomes will be standardised according to the Swedish national guidelines for bladder cancer regarding recommended follow-up intervals. For the study population this means control with cystoscopy every third month for two years, every sixth month the following three years and then annually with a lifelong follow up.

**Completion date**

30/06/2026

**Eligibility****Key inclusion criteria**

Bladder cancer subjected to transurethral resection of the tumour (TURB)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

26/11/2018

**Date of final enrolment**

30/06/2026

**Locations****Countries of recruitment**

Sweden

**Study participating centre****Malmö University Hospital**

Dept. of Urology, Jan Waldenströmsgata 5

Malmö

Sweden

205 02

**Study participating centre****Landskrona Hospital**

Region Skåne

Department of Urology

Vattenverksallén

Landskrona

Sweden

261 36

**Study participating centre****Helsingborg Hospital**

Department of urology

Charlotte Yhlens gata 10

Helsingborg  
Sweden  
251 87

**Study participating centre**

**Ängelholm Hospital**  
Department of Urology  
Västersjögatan 12  
Ängelholm  
Sweden  
262 53

**Study participating centre**

**Central Hospital Kristianstad**  
Division of Urology  
J A Hedlunds väg 5  
Kristianstad  
Sweden  
291 33

**Study participating centre**

**Ljungby Hospital**  
Division of urology  
Kyrkogatan 2  
Ljungby  
Sweden  
341 35

**Study participating centre**

**Växjö Hospital**  
Division of Urology  
352 34 Växjö  
Växjö  
Sweden  
352 34

**Study participating centre**

**Blekinge Hospital**  
Division of Urology  
Lasarettsvägen  
Karlskrona

Sweden  
371 41

**Study participating centre**  
**Ystad Hospital**  
Division of Urology  
Kristianstadsvägen 3  
Ystad  
Sweden  
271 33

## Sponsor information

**Organisation**  
Skåne University Hospital

**ROR**  
<https://ror.org/02z31g829>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Cancerfonden

**Alternative Name(s)**  
Swedish Cancer Society

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
Sweden

**Funder Name**

BioCARE

**Funder Name**  
Krapperrup fond

**Funder Name**  
ALF

**Funder Name**  
MAS Cancer

## Results and Publications

**Individual participant data (IPD) sharing plan**  
The datasets generated during this study will be included in the subsequent results publication.

**IPD sharing plan summary**  
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes