

Prognostic value of molecular subtypes in bladder cancer

Submission date 07/01/2019	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/02/2019	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/12/2024	Condition category 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, 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 Waldenströmögata 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