Prognostic value of molecular subtypes in bladder cancer

Submission date 07/01/2019	Recruitment status Recruiting	Prospectively registered
		☐ Protocol
Registration date 18/02/2019	Overall study status Ongoing	Statistical analysis plan
		Results
Last Edited	Condition category	Individual participant data
19/12/2024	Cancer	[X] 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. Växsjö 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 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 Växsjö Hospital

Division of Urology 352 34 Växjö Växjö Sweden 352 34

Study participating centre Blekinge Hospital

Division of Urology Lasarettsvägen Karlskrona

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

Funder Name

Krapperup 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?

Participant information sheet Participant information sheet Date added Date added Peer reviewed? Patient-facing?