ISRCTN15459149 https://doi.org/10.1186/ISRCTN15459149

Prognostic value of molecular subtypes in bladder cancer

Submission date 07/01/2019	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 18/02/2019	**Overall study status** Ongoing	
Last Edited 19/12/2024	**Condition category** Cancer	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format

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 measure
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.

Secondary outcome measures
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.

Overall study start date

01/01/2017

Completion date
30/06/2026

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20,000

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
Sweden
371 41

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

Sponsor information

Organisation
Skåne University Hospital

Sponsor details
Department of Urology
Jan Waldenströmsgata 7
Malmö
Sweden
-
+46 (0)40 33 10 00
fredrik.liedberg@med.lu.se

Sponsor type
Not defined

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
Krapperup fond

Funder Name
ALF

Funder Name
MAS Cancer

Results and Publications

Publication and dissemination plan
The study protocol in Swedish will not be available online. The study will be published in a high-impact peer reviewed journal one year after study closure.

Intention to publish date
31/05/2027

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