

Circulating tumour cells in bladder cancer patients treated with chemotherapy and radical cystectomy – enumeration, characterization and evaluation of prognostic value (the CIRCH-study)

Submission date 22/03/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/01/2021	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

Survival after chemotherapy for bladder cancer either alone or in combination with surgery is generally limited. Prognostic markers, or biological characteristics, such as levels of a particular protein in the body, that can be used to predict the response of chemotherapy treatment are currently lacking. This study investigates the number of, and characteristics of, circulating tumour cells (CTCs) in patients with bladder cancer receiving cisplatin-based combination chemotherapy. The aim is to see whether the presence and alterations of CTC-levels during chemotherapy are associated with progression-free survival (that is the time taken from after the treatment to progression of the disease).

Who can participate?

Adults with advanced bladder cancer undergoing chemotherapy.

What does the study involve?

Patients are observed for up to two years during and after their chemotherapy treatment. Blood samples are taken and analysed for CTCs throughout the study.

What are the possible benefits and risks of participating?

The risks of participating in the study is connected with blood sampling only.

Where is the study run from?

Skåne University Hospital (Sweden)

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

March 2016 to December 2019

Who is funding the study?
Lund University (Sweden)

Who is the main contact?
Dr Fredrik Liedberg
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
CIRculating tumour cells in bladder cancer patients treated with CHEmotherapy and radical cystectomy – enumeration, characterization and evaluation of prognostic value: a prospective investigational study

Acronym
CIRCH-study

Study objectives
Evaluate if presence and alterations of circulating tumour cell (CTC)-levels during chemotherapy are associated with progression-free survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Department 1, Lund University, 21/02/2013, ref: 2013/76

Primary study design

Observational

Study design

Prospective investigational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Urothelial carcinoma

Interventions

Patients are recruited when treatment with chemotherapy either neoadjuvant as induction chemotherapy or in a palliative setting is considered. The levels of circulating tumour cells are monitored for, under and after chemotherapy. The duration of observation includes a minimal of 2 years follow-up after study inclusion.

Intervention Type

Drug

Primary outcome(s)

Dynamic change in CTC during chemotherapy, using the Cellsearch method

Key secondary outcome(s)

1. Progression Free Survival (PFS) from date of chemotherapy start to progression/death (via patient chart review, using clinical and radiological (RESIST 1.1) criteria.)
2. Overall Survival (OS), measured as death from any cause

Completion date

30/12/2019

Eligibility

Key inclusion criteria

Locally advanced high grade urothelial carcinoma of the bladder scheduled for chemotherapy in the following settings; neoadjuvant, induction or palliative

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Other malignant diseases

Date of first enrolment

17/03/2016

Date of final enrolment

31/12/2019

Locations

Countries of recruitment

Sweden

Study participating centre

Skåne University Hospital

Department of Urology

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Sweden

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Sponsor information

Organisation

Lund University

ROR

<https://ror.org/012a77v79>

Funder(s)

Funder type

University/education

Funder Name

Lund University (Sweden)

Funder Name

Cancerfonden (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date