ISRCTN72499664 https://doi.org/10.1186/ISRCTN72499664

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

Registration date
18/05/2016

Overall study status
Completed

Last Edited
21/01/2021

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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(updated 21/01/2021, previously: fredrik.liedberg@skane.se)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Prospective investigational

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
Dynamic change in CTC during chemotherapy, using the Cellsearch method

Secondary outcome measures
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

Overall study start date

09/03/2016

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

Age group
Adult

Sex
Both

Target number of participants
Bladder cancer with planned chemotherapy as neoadjuvant, induction or palliative intent.

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
Jan Waldenströmsgata 5
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Sponsor information

Organisation
Lund University

Sponsor details
Institute Translational Medicine
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Sponsor type
University/education

ROR
https://ror.org/012a77v79

Funder(s)

Funder type
University/education

Funder Name
Lund University (Sweden)

Funder Name
Cancerfonden (Sweden)

Results and Publications

Publication and dissemination plan
Publication of current study will take place at the end of follow-up (2021)

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date