

Factors impacting on prognosis and treatment in patients with liver and lung metastases from colorectal cancer

Submission date 29/11/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/01/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/06/2019	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

Colorectal cancer means cancer that starts in the colon (large bowel) or back passage (rectum). It is a common cancer, and in about half of patients it will spread to the liver (liver metastases). For patients with liver metastases the only treatment with long-term survival is surgery. It is however less well studied as to how many of those patients will also develop lung metastases, and above all which treatment will be the most beneficial. The aim of this study is to find out whether lung surgery improves survival, compared to chemotherapy, for patients with liver and lung metastases from colorectal cancer.

Who can participate?

All patients with liver and lung metastases from colorectal cancer

What does the study involve?

Data is gathered from the Swedish Colorectal Cancer Registry from 2007 to 2016, from the Swedish Liver Registry from 2008 to 2016 and from the Swedish Thoracic Registry from 2009 to 2016. Data is also gathered from the In Patients Registry and from the Death Registry from 2007 to 2016. The study period is from 2007 to 2016. From these registries all patients with liver and lung metastases from colorectal cancer are identified. The main study questions is whether there is any difference in survival depending on the type of treatment for liver and lung metastases and if there is any factor that may affect survival. The aim is to find out whether liver and lung surgery for patients with colorectal cancer results in an improved survival compared to liver surgery and palliative chemotherapy for lung metastases.

What are the possible benefits and risks of participating?

There are no benefits or risks for participants as the study only uses data gathered from registries.

Where is the study run from?

1. Linköping University Hospital (Sweden)
2. Lund University Hospital (Sweden)

3. Karolinska University Hospital (Sweden)
4. Uppsala University Hospital (Sweden)
5. Umeå University Hospital (Sweden)
6. Sahlgrenska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
June 2017 to June 2020

Who is funding the study?
Linköping University Hospital

Who is the main contact?
Dr Kristina Hasselgren
Kristina.Hasselgren@liu.se

Contact information

Type(s)
Scientific

Contact name
Dr Kristina Hasselgren

ORCID ID
<http://orcid.org/0000-0002-0792-1588>

Contact details
Linköping University Hospital
Garnisonsvägen
Linköping
Sweden
581 85
+46 (0)10 1030000
Kristina.Hasselgren@liu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Factors impacting on prognosis and treatment in patients with liver and lung metastases from colorectal cancer - a Swedish national study

Study objectives

The aim of the study is to evaluate whether patients with liver and lung metastases from colorectal cancer have an improved survival if they are treated with liver and lung surgery compared to liver surgery and palliative chemotherapy for lung metastases.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Regional Ethical Review Board in Linköping, 09/20/2017, ref 2017/363-31

Study design

The study is a national registry study based on data from the Swedish Colorectal Cancer Registry (SCRCR), The Swedish Liver Registry (Sweliv) and The Swedish Thoracic Registry (ThoR)

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Patients with liver and lung metastases from colorectal cancer

Interventions

Data will be gathered from the Swedish Colorectal Cancer Registry from 2007 to 2016, from the Swedish Liver Registry from 2008 to 2016 and from the Swedish Thoracic Registry from 2009 to 2016. Data will also be gathered from the In Patients Registry and from the Death Registry from 2007 to 2016. The study period will be from 2007 to 2016. From these registries all patients with liver- and lung metastases from colorectal cancer will be identified. The main study questions are whether there is any difference in survival depending on treatment of liver- and lung metastases (resection, ablation, stereotactic body radiation therapy or chemotherapy) and if there is any prognostic factor that may affect the survival. The primary aim is to study whether liver and lung surgery for patients with colorectal cancer results in an improved survival compared to liver surgery and palliative chemotherapy for lung metastases.

Intervention Type

Procedure/Surgery

Primary outcome measure

Survival estimated from time of the diagnosis of the primary tumor, and for patients with metachronous liver metastases from the diagnosis of the liver metastases

Secondary outcome measures

Factors, beside surgery, that have an impact on prognosis and survival

Overall study start date

01/06/2017

Completion date

30/06/2020

Eligibility

Key inclusion criteria

All patients with liver and lung metastases from colorectal cancer

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

300

Key exclusion criteria

Other diagnoses than colorectal cancer

Date of first enrolment

01/01/2008

Date of final enrolment

31/12/2016

Locations

Countries of recruitment

Sweden

Study participating centre

Linköping University Hospital
Linköping
Sweden
581 85

Study participating centre
Lund University Hospital
Lund
Sweden
222 41

Study participating centre
Karolinska University Hospital
Stockholm
Sweden
171 76

Study participating centre
Uppsala University Hospital
Uppsala
Sweden
751 85

Study participating centre
Umeå University Hospital
Umeå
Sweden
907 37

Study participating centre
Sahlgrenska University Hospital
Gothenburg
Sweden
431 80

Sponsor information

Organisation

Region Östergötland

Sponsor details

Linköping University Hospital

Garnisonsvägen

Linköping

Sweden

581 85

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/0326gsy75>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Linköping University Hospital

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

30/06/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Per Sandström (per.sandstrom@liu.se).

IPD sharing plan summary

Available on request