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Influence of primary tumour resection on the course of disease in patients with metastatic colon cancer and unresectable metastases

Submission date 08/01/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 18/02/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 25/07/2016	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
When cancer spreads from the part of the body where it started (the primary tumour) to other parts of the body, these tumours are called metastases. Some tumours can be removed (resected) by surgery but some cannot (unresectable). Currently it is unclear whether patients with colon cancer and unresectable metastases should have the primary tumour resected before undergoing chemotherapy. Surgery delays the start of chemotherapy and bears a risk of severe complications and death, but it may prolong survival. The aim of this study is to find out whether primary tumour resection before chemotherapy prolongs the survival of patients with colon cancer.

Who can participate?
Patients aged 18 or over, recently diagnosed with colon cancer with unresectable metastases.

What does the study involve?
Participants are randomly allocated to one of two groups. One group undergoes surgical resection of the primary tumour before undergoing chemotherapy. The other group undergoes chemotherapy without resection of the primary tumour. Participants' survival is assessed with a minimum follow-up of 36 months.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital Carl Gustav Carus Dresden (Germany)

When is the study starting and how long is it expected to run for?
September 2011 to December 2019

Who is funding the study?
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

Who is the main contact?
Prof Jürgen Weitz
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Study website
http://www.synchronous-trial.de

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
Resection of the primary tumour versus no resection prior to systemic therapy in patients with colon cancer and synchronous unresectable metastases (UICC stage IV): a randomised controlled multicentre trial

Acronym
SYNCHRONOUS

Study objectives

Hypothesis as of 25/07/2016:
Resection of the primary tumour prolongs survival from 15 to 21 months compared to systemic therapy without prior tumour resection.

Original hypothesis:
Resection of the primary tumour prolongs survival from 20 to 26 months compared to systemic therapy without prior tumour resection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained from the Ethics Board of the Medical Faculty at the University of Heidelberg on 08/04/2011. Amendment 1 was voted positive on 26/06/2012. Amendment 2 was voted positive on 28/01/2015.

Study design
Prospective randomised controlled open multicentre trial with two parallel study groups

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Synchronous metastatic colon cancer not amenable for curative therapy

Interventions
Experimental arm: Surgical resection of the primary tumour prior to systemic therapy
Control arm: Systemic therapy without previous resection of the primary tumour

The duration of follow-up is 36 months for both arms.

Intervention Type
Mixed

Primary outcome measure

Overall survival is measured by follow up visits every 6 months up to 36 months and documented by participating hospitals in the eCRF (QoL questionnaire, medical treatment record, laboratory values of tumour markers; in case of death additional information on date cause of death is required).

Secondary outcome measures
1. Time-to-development of primary tumour complications (control arm), assessed until the end of the trial
2. Kind of primary tumour complications (control arm), assessed until the end of the trial
3. Need for intervention due to primary tumour complication (control arm), assessed until the end of the trial
4. Peri-operative morbidity (experimental arm) at 30 days after surgery
5. Peri-operative mortality (experimental arm) at 30 days after surgery
6. Interventions with curative intent (experimental and control arm), assessed until the end of the trial
7. Quality of life (EORTC QLQ C30 and CR29) at three months and six months after randomisation and then every six months

Overall study start date
31/01/2011

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Newly diagnosed, histologically confirmed colon cancer and/or high rectal cancer
2. Synchronous metastases not amenable for curative therapy; assessment by a local tumour board at each trial centre consisting of a surgeon, a medical oncologist or gastroenterologist and a radiologist
3. Resectable primary tumour
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, 2
5. Adequate medical condition to tolerate surgery and/or chemotherapy
6. Age greater than or equal to 18 years
7. Given informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
392

Key exclusion criteria
1. Rectal cancer (tumor up to 12 cm from the anal verge)
2. Tumour-related symptoms requiring urgent surgery
3. Patients not eligible for surgery (American Society of Anaesthesiologists [ASA] greater than or equal to IV)
4. Unequivocal extensive peritoneal metastases, i.e., lower gastrointestinal bleeding requiring transfusion, bowel obstruction, tumour perforation or intractable pain at site of primary tumour
5. Chemotherapy or radiotherapy during the past 6 months
6. History of another primary cancer. Exceptions: curatively treated in situ cervical cancer, curatively resected non-melanoma skin cancer or other primary solid tumour curatively treated with no known active disease present and no treatment administered for greater than or equal to 5 years prior to randomisation.
7. Expected lack of compliance

Date of first enrolment
01/09/2011

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
Austria

Germany

Study participating centre
University Hospital Carl Gustav Carus Dresden
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Sponsor information

Organisation
University Hospital Heidelberg

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Sponsor type
University/education

Website
http://www.uni-heidelberg.de

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
Research council

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Trial results will be published in a peer reviewed international journal, if possible with in a journal with a high impact factor.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/04/2012		Yes	No