

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

<b>Submission date</b> 08/01/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/07/2016	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
Direktor-VTG-Chirurgie@uniklinikum-dresden.de

**Study website**

<http://www.synchronous-trial.de>

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Jürgen Weitz

**Contact details**

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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

Fetscherstraße 74

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**Sponsor information****Organisation**

University Hospital Heidelberg

**Sponsor details**

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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?
<a href="#">Protocol article</a>	protocol	05/04/2012		Yes	No