

**KURZPROTOKOLL**  
**Synchronous**

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| <b>Öffentlicher Titel</b>   | Einfluss der Resektion des Primärtumors vor Beginn einer Chemotherapie auf den Krankheitsverlauf beim synchron metastasierten Kolonkarzinom in der Palliativsituation                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Wissenschaftl. Titel</b> | 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                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Kurztitel</b>            | Synchronous                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Studienart</b>           | multizentrisch, prospektiv, randomisiert, zweiarmig, kontrolliert, Investigator Initiated Trial (IIT)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Studienphase</b>         | Phase III                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Erkrankung</b>           | Verdauung: Darmkrebs (Kolorektales Karzinom): adjuvant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Einschlusskriterien</b>  | <ul style="list-style-type: none"><li>- Newly diagnosed, histologically confirmed colon cancer and / or high rectal cancer</li><li>- Synchronous metastases not amenable for curative therapy</li><li>- Resectable primary tumour</li><li>- ECOG performance status of 0, 1, 2</li><li>- <math>\geq 18</math> years of age</li><li>- Given informed consent</li><li>- Patient considered to tolerate or chemotherapy</li></ul>                                                                                                                                                                                           |
| <b>Ausschlusskriterien</b>  | <ul style="list-style-type: none"><li>- Mid / low rectal cancer (tumour up to 12 cm from the anal verge)</li><li>- Tumour related symptoms requiring urgent surgery</li><li>- Patients not eligible for surgery (ASA <math>\geq</math> IV)</li><li>- Chemo- or radiotherapy during the past 6 months</li><li>- History of another primary cancer</li><li>- Expected lack of compliance</li><li>- Unequivocal extensive peritoneal metastases</li><li>- Patients`participating in other clinical trials are not excluded provided there is no interference concerning clinical endpoints or protocol compliance</li></ul> |
| <b>Alter</b>                | 18 Jahre und älter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Fallzahl</b>             | 800                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Sponsor</b>              | Universitätsklinikum Heidelberg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Förderer</b>             | Deutsche Forschungsgemeinschaft                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |