

**KURZPROTOKOLL**  
**ESOPEC**

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| <b>Öffentlicher Titel</b>                        | Perioperative Chemotherapie versus neoadjuvanter Radiochemotherapie beim Ösophaguskarzinom                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Wissenschaftl. Titel</b>                      | Perioperative Chemotherapy (FLOT Protocol) Compared to Neoadjuvant Chemoradiation (CROSS Protocol) in Patients with Adenocarcinoma of the Esophagus                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Kurztitel</b>                                 | ESOPEC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Studienart</b>                                | multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Studienphase</b>                              | Phase III                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Erkrankung</b>                                | Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie<br>Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): neoadjuvant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Einschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Histologically verified adenocarcinoma of the esophagus according to the UICC definition (TNM7)</li><li>- Pre-treatment stage cT1N+, M0 or cT2-4a, N0/+, M0</li><li>- Age <math>\geq 18</math> years</li><li>- No prior abdominal or thoracic radiotherapy</li><li>- ECOG Performance status 0-2</li><li>- Adequate cardiac function (Patients with a cardiac history (e.g. myocardial infarction, heart failure, coronary artery disease) should have a cardiology review)</li><li>- Adequate bone marrow function (WBC <math>&gt; 3 \times 10^9/l</math>; Hb <math>&gt; 9 g/dl</math>; platelets <math>&gt; 100 \times 10^9/l</math>)</li><li>- Adequate respiratory function. Symptomatic Patients should have pulmonary function tests with FEV1 <math>&lt; 1,5l</math>)</li><li>- Adequate renal function (GFR <math>&gt; 60 ml/min</math>)</li><li>- Adequate liver function (serum bilirubin <math>&lt; 1.5 \times</math> Upper level of Normal (ULN); AST <math>&lt; 2.5 \times</math> ULN and ALT <math>&lt; 3 \times</math> ULN (ULN as per institutional standard))</li><li>- written informed consent</li></ul> |
| <b>Ausschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Tumors of squamous or other non-adenocarcinoma histology</li><li>- Patients with advanced inoperable or metastatic esophageal adenocarcinoma</li><li>- Stage cT1N0 and cT4b</li><li>- Gastric carcinoma</li><li>- Prior chemotherapy for cancer</li><li>- Clinically significant (i.e. active) cardiac disease (e.g. symptomatic coronary artery disease or myocardial infarction within last 12 months)</li><li>- Clinical significant lung disease (FEV1 <math>&lt; 1,5l</math>)</li><li>- Peripheral neuropathy Grade <math>&gt; 1</math></li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Alter</b>                                     | 18 Jahre und älter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Sponsor</b>                                   | Universitätsklinikum Freiburg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Registrierung in anderen Studienregistern</b> | ClinicalTrials.gov NCT02509286<br>EudraCT 2015-001683-20                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |