

KURZPROTOKOLL
ESOPEC

Öffentlicher Titel	Perioperative Chemotherapie versus neoadjuvanter Radiochemotherapie beim Ösophaguskarzinom
Wissenschaftl. Titel	Perioperative Chemotherapy (FLOT Protocol) Compared to Neoadjuvant Chemoradiation (CROSS Protocol) in Patients with Adenocarcinoma of the Esophagus
Kurztitel	ESOPEC
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): neoadjuvant
Einschlusskriterien	- Histologically verified adenocarcinoma of the esophagus according to the UICC definition (TNM7) - Pre-treatment stage cT1N+, M0 or cT2-4a, N0/+, M0 - Age ≥ 18 years - No prior abdominal or thoracic radiotherapy - ECOG Performance status 0-2 - Adequate cardiac function (Patients with a cardiac history (e.g. myocardial infarction, heart failure, coronary artery disease) should have a cardiology review) - Adequate bone marrow function (WBC $> 3 \times 10^9/l$; Hb $> 9g/dl$; platelets $> 100 \times 10^9/l$) - Adequate respiratory function. Symptomatic Patients should have pulmonary function tests with FEV1 $< 1,5l$) - Adequate renal function (GFR $> 60ml/min$) - Adequate liver function (serum bilirubin $< 1.5 \times$ Upper level of Normal (ULN); AST $< 2.5 \times$ ULN and ALT $< 3 \times$ ULN (ULN as per institutional standard) - written informed consent
Ausschlusskriterien	- Tumors of squamous or other non-adenocarcinoma histology - Patients with advanced inoperable or metastatic esophageal adenocarcinoma - Stage cT1N0 and cT4b - Gastric carcinoma - Prior chemotherapy for cancer - Clinically significant (i.e. active) cardiac disease (e.g. symptomatic coronary artery disease or myocardial infarction within last 12 months) - Clinical significant lung disease (FEV1 $< 1,5l$) - Peripheral neuropathy Grade > 1
Alter	18 Jahre und älter
Prüfzentren	Universitätsmedizin Frankfurt (Rekrutierung beendet) Klinik für Strahlentherapie und Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Detlef Imhoff Tel: 069 6301-5130 studien-strahlen@unimedizin-ffm.de
Sponsor	Universitätsklinikum Freiburg
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02509286 EudraCT 2015-001683-20