

KURZPROTOKOLL
FLOT 65+

Öffentlicher Titel	Phase II Studie zur Therapie des fortgeschrittenen Magen-/Ösophaguskarzinoms bei Patienten über 65 Jahre
Wissenschaftl. Titel	A multicenter, randomised phase II/III trial on the therapy of advanced gastric cancer or adenocarcinoma of the esophagogastric junction in patients older than 65 years with specific regard of quality of life and pharmacogenetic risk profile
Kurztitel	FLOT 65+
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
Ziele	<ul style="list-style-type: none">- Response rate- Prospective Validation of a pharmacogenetic risk profile for patients with advanced GC under first-line therapy with platin/docetaxel- Evaluation of quality of life- safety and tolerability progression free survival (PFS), time to treatment failure (TTF), overall survival (OS)
Einschlusskriterien	<ul style="list-style-type: none">- histologically confirmed metastatic (every T, every N, M1), locally advanced (uT4, every N, M0 or uT3, every N, M0 or every T, N3, M0) or refractory gastric cancer or adenocarcinoma of the esophagogastric junction- no prior chemotherapy in metastatic state- Female and Male Patients aged \geq 65 years- ECOG \leq 2- Leucocytes $>$ 3.000/μl- Thrombocytes $>$ 100.000/μl- Serumcreatinine \leq 1.5x of normal value or Creatinine-Clearance $>$ 40 ml/min- Written informed consent
Ausschlusskriterien	<ul style="list-style-type: none">- hypersensitivity for 5-FU, Leucovorin, Oxaliplatin or Docetaxel- KHK, cardiomyopathy or cardiac insufficiency Stage II-IV according to NYHA- malignancy $<$5 years ago- brain metastases- severe internal disease or acute infection- peripheral Polyneuropathy $>$ NCI Grade II- severe liver dysfunction (AST/ALT$>$3,5xULN, AP$>$6xULN, Bilirubin$>$1,5xULN)- inflammatory bowel disease- participation in other clinical trial
Alter	65 Jahre und älter
Status	Geschlossen
Registrierung in anderen Studienregistern	EudraCT 2006-006936-24 ClinicalTrials.gov NCT00737373 (primäres Register)