KURZPROTOKOLL
FLOT5

Öffentlicher Titel	Studie zu Chemotherapie vs Chemotherapie mit anschließender Resektion bei Adenokarzinom des Magens oder des ösophagogastrischen Übergangs
Wissenschaftl. Titel	Effect of chemotherapy alone vs. chemotherapy followed by surgical resection on survival and quality of life in patients with limited-metastatic adenocarcinoma of the stomach or esophagogastric junction - a phase III trial of AIO/CAO-V/CAOGI.
Kurztitel	FLOT5
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie

Einschlusskriterien

- Histologically confirmed limited metastatic gastric or GEJ adenocarcinoma.*
- Medical and technical operability of the primary.
- Metastatic lesions are resectable or can be controlled by local ablative procedure (central evaluation).
- No prior chemotherapy and no prior tumor resection.
- Female and male patients >= 18 years. Patients in reproductive age must be willing to use adequate contraception during the study and 3 months after the end of the study (appropriate contraception is defined as surgical sterilization (e.g., bilateral tubal ligation, vasectomy), hormonal contraception (implantable, patch, oral), and double-barrier methods (any double combination of: intrauterine device, male or female condom with spermicidal gel, diaphragm, sponge, cervical cap)). Female patients with childbearing potential need to have a negative pregnancy test within 7 days before study start.
- ECOG (Eastern Cooperative Oncology Group) Performance Status 0 or 1
- Adequate hematological, hepatic and renal function parameters: Leukocytes >= 3000/µl; Platelets 100,000/µl; Serum creatinine 1.5 x upper limit of normal, or glomerular filtration rate (GFR) > 40 ml/min; Bilirubin 1.5 x upper limit of normal; AST (aspartate aminotransferase) and ALT (alanine transaminase) 3.5 x upper limit of normal; Alkaline phosphatase 6 x upper limit of normal;
- Written informed consent of the patient.

Ausschlusskriterien

- Medical inoperability
- Inability to understand the aims of the study and/or protocol procedures
- Metastatic disease not fulfilling the criteria of limited disease mentioned in the inclusion criteria or non-metastatic stage (cM0)
- Primary not resectable
- Hypersensitivity to 5-fluorouracil, leucovorin, oxaliplatin, docetaxel, or trastuzumab (in HER-2 positive tumors)
- Contraindication versus 5-fluorouracil, leucovorin, oxaliplatin, docetaxel (see specific product information), or trastuzumab (in HER-2 positive tumors)
- Clinically significant active coronary heart disease, cardiomyopathy or congestive heart failure, NYHA (New York Heart Association) III-IV
- Clinically significant valvular defect
- Past or current history of other malignancies unless curatively treated and without evidence of disease for more than 3 years, except for curatively treated basal cell carcinoma of the skin and in situ carcinoma of the cervix
- Known brain metastases
- Other severe internal disease or acute infection
- Peripheral polyneuropathy > NCI grade II
- Serious hepatic impairment (AST/ALT>3.5xULN, AP>6xULN, bilirubin>1.5xULN; ULN = upper limit of normal)

- Chronic inflammatory bowel disease
- Any other concurrent antineoplastic treatment including irradiation
- Participation in another clinical study
- Participation in another clinical study

Alter	18 Jahre und älter
Status	Aktiv
Fallzahl	271
Prüfzentren	**Agaplesion Markus Krankenhaus** Wilhelm-Epstein-Straße 4 60431 Frankfurt am Main Dr. med. Claus Bolling Tel: 069 95332206 Fax: 069 95332098 claus.bolling@fdk.info **Klinikum Darmstadt GmbH** Grafenstraße 9 64283 Darmstadt Cora Schwebel-Kottke Tel: 06151 1076670 Fax: 06151 1076676 Onko-Studienzentrum@mail.klinikum-darmstadt.de **Universitätsklinikum Gießen und Marburg, Standort Marburg** Hämatologie, Onkologie und Immunologie Marburg Nina Marschalek Tel: 06421 58 63546 Fax: 06421 58 62703 studien-onkologie@uni-marburg.de **Krankenhaus Nordwest GmbH** Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Camilla Scherer Tel: 069 7601 4280 Fax: 069 7601 36 55 scherer.camilla@khnw.de
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Förderer	DFG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02578368 (primäres Register) EudraCT 2014-002665-30