KURZPROTOKOLL
FLOT6

Öffentlicher Titel	Phase II/III Studie zu FLOT vs FLOT/Herceptin/Perjeta zur perioperativen Behandlung bei Her2+ Adenokarzinom des Magens oder des ösophagogastrischen Übergangs
Wissenschaftl. Titel	FLOT vs. FLOT/Herceptin/Perjeta for perioperative therapy of adenocarcinoma of the stomach and gastroesophageal junction expressing HER-2. A phase II/III trial of the AIO
Kurztitel	FLOT6
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase II/III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
Einschlusskriterien	- Histologically confirmed adenocarcinoma of the GEJ (type I-III) or the stomach (uT2, uT3, uT4, any N category, M0), or any T N+ M0 patient, with the following specifications: Medical and technical operability; Centralized detection of either an adenocarcinoma with HER-2 3+ (IHC) or HER-2 2+ (IHC) with amplification proven by FISH, SISH or CISH - No preceding cytotoxic or targeted therapy - No prior partial or complete tumor resection - Exclusion of the infiltration of any adjacent organs or structures by CT or MRI - Exclusion of distant metastasis by CT or MRI of thorax and abdomen, and bone scan (if osseous lesions are suspected due to clinical signs) - Female and male patients 18 years. Patients in reproductive age must be willing to use adequate contraception during the study and for 7 months after the end of pertuzumab and Herceptin treatment (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: IUD, 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 2 - Laparoscopic exclusion of peritoneal carcinomatosis, if suspected clinically - Adequate haematological, hepatic and renal function parameters: Leukocytes 3.000/mm³, platelets 100.000/mm3; Serum creatinine 1.5 x upper limit of normal, or GFR > 40 ml/min; Bilirubin 1.5 x upper limit of normal, AST and ALT 3.5 x upper limit of normal, alkaline phosphatase 6 x upper limit of normal - LVEF value > 55 %, as assessed by echocardiography - Patient able and willing to provide written informed consent and to comply with the study protocol and with the planned surgical procedures
Ausschlusskriterien	- Patients with involved retroperitoneal (e.g. para-aortal, paracaval or interaortocaval lymph nodes) or mesenterial lymph nodes (distant metastasis!) - Known hypersensitivity against Herceptin, pertuzumab, 5-FU, leucovorin, oxaliplatin, or docetaxel - Other known contraindications against Herceptin, pertuzumab, 5-FU, leucovorin, oxaliplatin, or docetaxel - Documented history of congestive heart failure of any NYHA, myocardial infarction within the past 6 months before the first dose of study treatment - Clinically significant valvular defect , history of poorly controlled arterial hypertension (systolic blood pressure > 180 mmHG or diastolic blood pressure > 100 mmHg) or uncontrollable high-risk cardiac arrhythmia (i.e tachycardia with a heart rate > 100/min at rest), significant ventricular arrhythmia (ventricular tachycardia) or higher grade atrioventricular-block (second degree AV-block Type 2 (Mobitz2) or third degree AV-block)

	- Past or current history of other malignancies not curatively treated and without evidence of disease for more than 5 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 - Chronic inflammatory bowel disease - Clinically significant active GI bleeding - On-treatment participation in another clinical study in the period 30 days prior to inclusion and during the study - Subject pregnant or breast feeding, or planning to become pregnant within 6 months after the end of treatment. - Patients in a closed institution according to an authority or court decision (AMG § 40, Abs. 1 No. 4) - Any other concurrent antineoplastic treatment including irradiation
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Fallzahl	404
Sponsor	IKF GmbH
Förderer	Roche Pharma AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02581462 (primäres Register) EudraCT 2014-002695-86
Links	Zu den Ein- und Ausschlusskriterien