

## **KURZPROTOKOLL FLOT6**

<b>Öffentlicher Titel</b>	Phase II/III Studie zu FLOT vs FLOT/Herceptin/Perjeta zur perioperativen Behandlung bei Her2+ Adenokarzinom des Magens oder des ösophagogastrischen Übergangs
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	FLOT6
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
<b>Studienphase</b>	Phase II/III
<b>Erkrankung</b>	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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</li><li>- No preceding cytotoxic or targeted therapy</li><li>- No prior partial or complete tumor resection</li><li>- Exclusion of the infiltration of any adjacent organs or structures by CT or MRI</li><li>- Exclusion of distant metastasis by CT or MRI of thorax and abdomen, and bone scan (if osseous lesions are suspected due to clinical signs)</li><li>- 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.</li><li>- ECOG 2</li><li>- Laparoscopic exclusion of peritoneal carcinomatosis, if suspected clinically</li><li>- Adequate haematological, hepatic and renal function parameters: Leukocytes 3.000/mm<sup>3</sup>, platelets 100.000/mm<sup>3</sup>; Serum creatinine 1.5 x upper limit of normal, or GFR &gt; 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</li><li>- LVEF value &gt; 55 %, as assessed by echocardiography</li><li>- Patient able and willing to provide written informed consent and to comply with the study protocol and with the planned surgical procedures</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Patients with involved retroperitoneal (e.g. para-aortal, paracaval or interaortocaval lymph nodes) or mesenterial lymph nodes (distant metastasis!)</li><li>- Known hypersensitivity against Herceptin, pertuzumab, 5-FU, leucovorin, oxaliplatin, or docetaxel</li><li>- Other known contraindications against Herceptin, pertuzumab, 5-FU, leucovorin, oxaliplatin, or docetaxel</li><li>- Documented history of congestive heart failure of any NYHA, myocardial infarction within the past 6 months before the first dose of study treatment</li><li>- Clinically significant valvular defect, history of poorly controlled arterial hypertension (systolic blood pressure &gt; 180 mmHG or diastolic blood pressure &gt; 100 mmHG) or uncontrollable high-risk cardiac arrhythmia (i.e tachycardia with a heart rate &gt; 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)</li></ul>

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- 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

<b>Alter</b>	18 Jahre und älter
<b>Molekularer Marker</b>	HER2/neu pos.
<b>Fallzahl</b>	404
<b>Sponsor</b>	IKF GmbH
<b>Förderer</b>	Roche Pharma AG
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT02581462 (primäres Register) EudraCT 2014-002695-86
<b>Links</b>	<a href="#">Zu den Ein- und Ausschlusskriterien</a>