KURZPROTOKOLL
AIO-STO-0310

Öffentlicher Titel	Explorative Phase II Studie einer perioperativen Behandlung bei Adenokarzinom des gastroösophagealen Übergangs oder Magens
Wissenschaftl. Titel	Multicenter, Explorative Phase II Study of Perioperative 5-FU, Leucovorin, Docetaxel, and Oxaliplatin (FLOT) in Combination With Trastuzumab in Patients With HER2-positive, Locally Advanced, Resectable Adenocarcinoma of the Gastroesophageal Junction or Stomach (HerFLOT)
Kurztitel	AIO-STO-0310
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase II
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): neoadjuvant
Ziele	- Rate of complete pathological responses (percentage of patients with pCR referring to the total number of enrolled and eligible patients), as evaluated centrally by a reference pathologist. - The experimental therapy would be rated as insufficiently active, if the observed pCR rate is 10 % or lower, as this corresponds to the expectations after chemotherapy alone. The experimental therapy would be considered to be a promising candidate for further development (e.g. in a phase III trial), if the true pCR rate amounted to 20% or more. - R0 resection rate - The R0 rate is defined as the number of patients with negative surgical margins and no tumor left macroscopically, divided by the total number of recruited eligible patients. - Relapse-free survival - Relapse-free survival (RFS) will be defined as the time from enrolment to the time of disease progression or relapse or death, or to the date of last tumor assessment without any such event (censored observation) - Overall survival - The duration of overall survival (OS) will be determined by measuring the time interval from enrolment to the date of death or last observation, including survival rates after 1, 2 and 3 years.
Einschlusskriterien	- Histologically confirmed adenocarcinoma of the gastroesophageal junction (AEG I-III) or the stomach (uT2, uT3, uT4, any N category, M0), or any T N+ M0 patient, with the following specifications: - a. Endosonography and an esophageal-gastro-duodenoscopy; - b.Categorization of gastroesophageal junction tumors according to the classification by Siewert (1987, cf. appendix - Detection of an adenocarcinoma with HER2 3+ (IHC) or HER2 2+ (IHC) with amplification proven by FISH, SISH or CISH by an accredited local pathologist (for quality assurance tumor samples have to be available for a subsequent central review) - No preceding cytotoxic or targeted therapy - Male and female patients aged 18 years. - If able to reproduce, patients must be willing to use highly effective methods of contraception during treatment and for 6 months after the end of treatment (adequate: methods fulfilling the requirements of the Note for guidance on non-clinical safety studies for the conduct of human clinical trials for pharmaceuticals [CPMP/ICH/286/95 mod]). - Female patients with reproductive ability must have performed a negative pregnancy test within 7 days of study entry.

	- ECOG 2 Exclusion of distant metastasis by CT of thorax and abdomen, bone scan or MRI (if osseous lesions are suspected due to clinical signs) - Laparoscopic exclusion of peritoneal carcinomatosis, if suspected clinically - Adequate haematological, hepatic and renal function parameters: - a. Leukocytes 3000/mm³, - b. platelets 100,000/mm3; - c. Serum creatinine 1.5 x upper limit of normal, or - d. GFR > 40 ml/min; - e. Bilirubin 1.5 x upper limit of normal, - f. AST and ALT 3.5 x upper limit of normal, - g. alkaline phosphatase 6 x upper limit of normal - Normal cardiac ejection fraction, as assessed by echocardiography - Written patient consent form
Ausschlusskriterien	- Known hypersensitivity against trastuzumab, murine proteins, 5-FU, leucovorin, oxaliplatin or docetaxel - Other known contraindications against trastuzumab, 5-FU, leucovorin, oxaliplatin, or docetaxel - Clinically significant active coronary heart disease, cardiomyopathy or congestive heart failure, - NYHA III-IV - Clinically significant valvular defect - 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 - Severe dyspnoea at rest due to complications of advanced malignancy or requiring supplementary oxygen therapy - Other severe internal disease or acute infection - Peripheral polyneuropathy > NCI Grade II - Chronic inflammatory bowel disease - 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.
Sponsor	AIO-Studien GmbH (Hauptsponsor)
Förderer	AIO-Studien GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01472029 (primäres Register) EudraCT 2011-001507-13
Therapie	5-FU, leucovorin, docetaxel, oxaliplatin (FLOT), trastuzumab
Links	Studien im Krankenhaus Nordwest

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