KURZPROTOKOLL
HELOISE, BO27798

Öffentlicher Titel	Herceptin in Kombination mit Cisplatin/Capecitabine bei HER2neu-positiven, metastasierten Magen- oder AEG-Karzinomen
Wissenschaftl. Titel	A Study of Herceptin (Trastuzumab) in Combination With Cisplatin/Capecitabine Chemotherapy in Patients With HER2-Positive Metastatic Gastric or Gastro-Esophageal Junction Cancer
Kurztitel	HELOISE, BO27798
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
Ziele	- OS - duration of PFS - safety and tolerability
Einschlusskriterien	- Male or female. Age >= 18 years - Signed informed consent - Ability to comply with the protocol - confirmed adenocarcinoma of the stomach or gastro-esophageal junction with metastatic disease documented to involve at least two organs (at least liver or lung or both) - Measurable disease, according to the Response Evaluation Criteria in Solid Tumors (RECIST 1.1), assessed using imaging techniques (computed tomography [CT] or magnetic resonance imaging [MRI]), or non-measurable evaluable disease - At least 2 organs involved by metastatic gastric tumor (including at least lung or liver or both) - HER2-positive (defined as either IHC 3+ or IHC 2+/ISH+; with ISH-positivity defined as a ratio of 2.0 of HER2 gene copy number/number of signals for CEP17) primary or metastatic tumor, as assessed by central laboratory - Creatinine clearance (CrCl) >= 45 mL/min - ECOG Performance Status 2 - Life expectancy of at least 3 months
Ausschlusskriterien	- Previous chemotherapy for locally advanced or metastatic disease (prior adjuvant/neoadjuvant therapy is allowed if at least 6 months have elapsed between completion of adjuvant/neoadjuvant therapy and enrollment into the study) - Prior gastrectomy (partial or total) for the underlying malignant disease under investigation - Prior adjuvant or neoadjuvant therapy with an anti-HER2 agent and/or a platinum salt - Lack of physical integrity of the upper gastrointestinal tract or malabsorption syndrome (eg, patients with a jejunostomy probe, gastric or jejunostomy tubes). This is because capecitabine is an orally administered drug - Current (significant or uncontrolled) gastrointestinal bleeding - Residual relevant toxicity resulting from previous therapy (with the exception of alopecia), eg, hematological or neurological toxicity Grade 2 (NCI-CTCAE), except stable neurological deficit due to treatment occurring 5 years earlier - Other malignancy within the last 5 years, except for carcinoma in situ of the cervix or squamous cell carcinoma of the skin - Absolute Neutrophil count (ANC) < 1.5 × 109/L, or platelet count < 100 × 109/L - Total bilirubin > 1.5 × upper limit of normal (ULN); or, AST or ALT > 2.5 × ULN (or > 5 × ULN in patients with liver metastases)

- Alkaline phosphatase > 2.5 × ULN (or > 5 × ULN in patients with liver metastases, or > 10 × ULN in patients with bone but no liver metastases)
- History of documented congestive heart failure; angina pectoris requiring medication; electrocardiogram (ECG) evidence of trans-mural myocardial infarction; poorly controlled hypertension (systolic blood pressure [BP] > 180 mmHg or diastolic BP > 100 mmHg); clinically significant valvular heart disease; or high risk uncontrollable arrhythmias
- Baseline LVEF < 50 % (documented by echocardiography, MUGA scan, or cardiac MRI)
- Dyspnea at rest due to complications of advanced malignancy or other disease, or requiring supplemental oxygen therapy
- Receiving chronic or high-dose corticosteroid therapy (inhaled steroids or clinically indicated short courses of oral steroids are allowed)
- Clinically significant hearing abnormality
- Known dihydropyrimidine dehydrogenase (DPD) deficiency
- History or clinical evidence of brain metastases
- Serious uncontrolled systemic intercurrent illness, eg, active infection or poorly controlled diabetes
- Positive serum pregnancy test
- Male or female of reproductive potential who is unwilling to use an adequate contraceptive measure during study medication. Examples of adequate contraceptive measures are intra-uterine device, barrier method (condoms, diaphragm), also in conjunction with spermicidal jelly, or total abstinence. Oral, injectable, or implant hormonal contraceptives are not acceptable
- Received any investigational treatment within 4 weeks before start of study treatment
- Received radiotherapy within 4 weeks before start of study treatment (2 weeks interval allowed following palliative radiotherapy given to peripheral bone metastastic site if patient has recovered from all acute toxicities)
- Major surgery within 4 weeks before start of study treatment, without complete recovery
- Known active infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV), or known HIV-seropositivity
- Known hypersensitivity to any study drugs

Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Status	Geschlossen
Fallzahl	400
Sponsor	Hoffmann-La Roche Ltd
Förderer	Hoffmann-La Roche Ltd
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01450696 EudraCT 2011-001526-19
Therapie	Active Comparator: A Interventions: Drug: trastuzumab [Herceptin] Drug: capecitabine Drug: cisplatin Experimental: B Interventions: Drug: trastuzumab [Herceptin] Drug: capecitabine Drug: cisplatin
Links	Institut für Klinische Forschung am Krankenhaus Nordwest