

KURZPROTOKOLL
ML22834 Hermes

Öffentlicher Titel	Beobachtungsstudie zu Trastuzumab bei HER2-positivem fortgeschrittenem Magenkrebs
Wissenschaftl. Titel	Clinical Practice Surveillance of the Use of Herceptin in Patients With HER2-positive Advanced Adenocarcinoma of the Stomach or Gastro-esophageal Junction (GEJ) (HERMES)
Kurztitel	ML22834 Hermes
Studienart	multizentrisch, Anwendungsbeobachtung, prospektiv, offen/unverblindet, Pharma-Studie
Studienphase	nicht zutreffend
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): weitere
Ziele	<ul style="list-style-type: none">- Response rate according to Response Evaluation Criteria in Solid Tumors (RECIST)- Progression-free survival according to Response Evaluation Criteria in Solid Tumors (RECIST)- ein Ziel- Overall survival according to Response Evaluation Criteria in Solid Tumors (RECIST)- Documentation of the testing process for HER2-positive tumors- Assessment of implementation of guidelines and recommendations of Herceptin administration in routine clinical practice- Documentation of backbone chemotherapy treatment and concomitant medication- Quality of Life questionnaire- Surveillance of pain intensity and analgesic consumption Surveillance of weight change- Safety (incidence of adverse events)
Einschlusskriterien	<ul style="list-style-type: none">- Adult patients, ≥ 18 years of age- Histologically confirmed advanced adenocarcinoma of the stomach or gastro-esophageal junction (GEJ) with locally advanced and/or metastatic disease HER2-positive tumor- Patients who are eligible for treatment with Herceptin according to the judgment of the physician
Ausschlusskriterien	<ul style="list-style-type: none">- Unwilling or unable to sign informed consent form- Any contraindications, interactions and incompatibilities to Herceptin
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Sponsor	Roche Pharma AG (Hauptsponsor)
Förderer	Roche Pharma AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01220934 (primäres Register)