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	- 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	- 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	- 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)