KURZPROTOKOLL
Re-ExPEL

Öffentlicher Titel	Ramucirumab und TAS-102 zur Zweitlinientherapie eines fortgeschrittenen Adenokarzinoms des Magens oder des ösophagealen Übergangs
Wissenschaftl. Titel	A pilot study of ramucirumab beyond progression plus TAS-102 in patients with advanced or metastatic adenocarcinoma of the stomach or the gastroesophageal junction, after treatment failure on a ramucirumab based therapy
Kurztitel	Re-ExPEL
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)
Studienphase	nicht zutreffend
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Zweitlinie oder höher
Einschlusskriterien	- Signed informed consent form - Men or women* >= 18 years of age. Patients of reproductive age must be prepared to use a suitable contraceptive method during the study and up to 6 months after the end of treatment. A suitable method of contraception is defined as surgical sterilization (e.g. bilateral fallopian tube ligation, vasectomy), hormonal contraception (implantable, patch, oral), and double barrier methods (each two-fold combination of intrauterine pessary, condom for men, or women with spermicidal gel, diaphragm, contraceptive sponge, cervical cap). Women of child-bearing potential must have a negative pregnancy test within the last 7 days prior to the start of study therapy. *There is no data that indicates a specific gender distribution. Therefore, patients are included regardless of their gender - Histologically proven adenocarcinoma of the stomach, including adenocarcinoma of the gastroesophageal junction (note: previous histological assessment during disease history of patient sufficient, current biopsy during screening for this trial is not mandatory) - Documented, objective, radiological or clinical progression of the disease during or within 4-6 weeks after the last dose of a ramucirumab based second-line therapy (ramucirumab monotherapy or a combination of ramucirumab + paclitaxel, respectively ramucirumab + FOLFIRI) - Measurable or non-measurable but evaluable disease - ECOG Performance status 0-2 - Life expectancy > 8 weeks - Appropriate haematological, hepatic and renal function: Absolute number of neutrophils (ANC) >= 1.5 x 10^9/L Platelets >= 100 x 10^9/L Hemoglobin >= 9 g/dL (5.58 mmol/L) Total bilirubin <= 1.5 times the upper limit of normal (UNL) AST (SGOT) and ALT (SGPT) <= 2.5 x UNL without existing liver metastases, or <= 5 x UNL in the presence of liver metastases; AP <= 5 x UNL - Serum creatinine <= 1.5 x UNL or creatinine clearance (measured by 24h urine) >= 40 mL / min (i.e. if the serum creatinine level is > 1.5 x UNL, then a 24h urine test must be performed to check the creatinine clearance to be determined). Protein level in urine <= 1+ by dipstick analysis or routine urine measurement (if the dipstick analysis or the routine test >= 2+, a subsequent 24h urine protein measurement must show a value of < 1000mg of protein within 24h of participation to ensure the study - Adequate coagulability, as determined by the International Normalized Ratio (INR) <= 1.5 and partial thromboplastin time (PTT) <= 5 seconds above the UNL (unless anti-coagulation therapy has been given). Patients receiving warfarin / phenoprocoumon must be switched to low molecular weight heparin and must have a stable coagulation profile before starting study-specific therapy - Subject is willing and able to comply with the protocol (including contraceptive measures) for the duration of the study including undergoing treatment and scheduled visits and examinations including follow up

Ausschlusskriterien

- Presence of tumors other than adenocarcinomas (e.g., leiomyosarcoma, lymphoma) or a secondary tumor other than squamous or basal cell carcinomas of the skin or in situ carcinomas of the cervix which have been effectively treated. The sponsor decides to include patients who have received curative treatment and have been disease-free for at least 5 years
- Squamous cell carcinoma of the stomach or gastroesophageal junction
- Simultaneous, ongoing, systemic immunotherapy, chemotherapy, or hormone therapy not described in the study protocol
- Simultaneous treatment with a different anti-cancer therapy other than that provided for in the study (excluding palliative radiotherapy for symptom control)
- The patient is receiving chronic antiplatelet therapy, including aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs, including ibuprofen, naproxen, and others), dipyridamole or clopidogrel, or similar agents. Once-daily aspirin use (maximum dose 325 mg/day) is permitted
- The patient has undergone major surgery within the last 28 days prior to the start of study-specific therapy or has undergone minor surgery within the last 7 days prior to the start of study therapy. The patient had subcutaneous venous access within the last 7 days prior to the start of the study-specific therapy. The patient plans to undergo major surgery while participating in the clinical trial
- Gastrointestinal bleeding grade 3-4 within the last 3 months prior to enrollment in the study
- History of deep vein thrombosis (DVT), pulmonary embolism (PE), or any other clinically important thromboembolic event during the last 3 months prior to the start of study-specific therapy (thrombosis caused by venous ports, catheters, or superficial venous thrombosis are not considered "clinically meaningful")
- Stage B cirrhosis according to Child-Pugh criteria (or worse) or cirrhosis (of any grade) with a history of hepatic encephalopathy or clinically significant ascites resulting from cirrhosis. Clinically significant ascites is defined as ascites resulting from cirrhosis requiring diuretics or paracentesis
- Known brain or leptomeningeal metastases
- Known allergic / hypersensitive reactions to at least one of the treatment components
- Other serious illnesses or medical ailments within the last 12 months prior to the start of the study
- Any arterial thromboembolic event which includes, but is not limited to, the following: myocardial infarction, transient ischemic attack, cerebrovascular insult, unstable angina within the last 6 months prior to the initiation of study therapy
- Uncontrolled or under-adjusted hypertension (> 160 mmHg systolic or > 100 mmHg diastolic hypertension for more than 4 weeks) despite standard medical treatment
- Presence of an active, uncontrollable infection
- Chronic inflammatory bowel disease
- Active disseminated intravascular coagulation
- Any other serious concomitant or medical condition that, in the opinion of the investigator, presents a high risk of complications to the patient or reduces the likelihood of clinical effect
- Known dihydropyrimidine dehydrogenase (DPD) deficiency
- History of gastrointestinal perforation / fistula (within the last 6 months prior to the start of study-specific therapy) or presence of risk factors favoring perforation
- Serious or non-healing wounds, ulcers, or broken bones within the last 28 days prior to the start of study-specific therapy
- The patient is pregnant or breast-feeding

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Alter	18 - 99 Jahre
Prüfzentren	**Krankenhaus Nordwest GmbH** (Rekrutierung beendet) Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Heike Mohn Tel: 069 7601 4072 mohn.heike@khnw.de
Sponsor	IKF GmbH
Förderer	Eli Lilly and Company
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04517747 (primäres Register)
Links	Zu den Ein- und Ausschlusskriterien