

KURZPROTOKOLL **PARLIM**

Öffentlicher Titel	Panitumumab nach Resektion von kolorektalen Lebermetastasen mit RAS -Wildtyp
Wissenschaftl. Titel	Panitumumab nach Resektion von Lebermetastasen des kolorektalen Karzinoms bei Patienten mit RAS -Wildtyp
Kurztitel	PARLIM
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Verdauung: Darmkrebs (Kolorektales Karzinom): adjuvant
Einschlusskriterien	- Patient has provided written informed consent. - R0-resection of liver metastasis, at least four weeks but not longer than 8 weeks ago. - Histologically confirmed diagnosis of metastatic colorectal cancer confined to the liver - KRAS-wildtype of the tumor - Age 18 years or older - ECOG performance status 0-1 - Females with child-bearing potential must use adequate contraceptive measures - Exclusion of pregnancy - Relevant toxicities of previous treatments must have subsided - Magnesium $\geq$ lower limit of normal; Calcium $\geq$ lower limit of normal - Normal cardiac function demonstrated by ECG and echocardiogram (LVEF $\geq$ 55%): (a) No symptomatic congestive heart failure; (b) No unstable angina pectoris; (c) No cardiac arrhythmia - Adequate organ function as defined by Table 1: (a) Hematologic: ANC (absolute neutrophil count) $\geq$ 1.5 G/L, Leucocytes $>$ 3.0 G/L, Hemoglobin $\geq$ 9 g/dL, Platelets $\geq$ 100 G/L; (b) Hepatic: Albumin $\geq$ 2.5 g/dL, Serum bilirubin $\leq$ 2 mg/dL, AST and ALT $\leq$ 3 x ULN; (c) Renal: Serum Creatinine $\leq$ 1.5 mg/dL
Ausschlusskriterien	- Known manifestations of metastatic disease - Progression during preoperative treatment - Missing KRAS mutation status of the tumor - Contraindication against therapy with 5-fluorouracil/ folinic acid or oxaliplatin - Known intolerance of panitumumab - Known DPD deficiency - Polyneuropathy $>$ grade 1 (NCI-CTCv4) which precludes the use of oxaliplatin - Evidence of ascites or cirrhosis - Patient is pregnant or lactating or planning to become pregnant within 6 months after end of treatment - Subject (male or female) is not willing to use highly effective methods of contraception (per institutional standard) during treatment and for 6 months (male or female) after the end of treatment - Has had a major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to study enrolment, or there is an anticipated need for major surgical procedure during the course of the study - Clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) $\leq$ 1 year before enrolment/randomization - History of interstitial lung disease e.g. pneumonitis or pulmonary fibrosis or evidence of interstitial lung disease on baseline chest CT scan

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- Has a concurrent disease or condition that would make the subject inappropriate for study participation or would interfere with the subject's safety.
- Has any psychological, familial, sociological, or geographical conditions that do not permit compliance with the protocol.
- Requires concurrent cancer therapy (chemotherapy, radiation therapy, biologic therapy, immunotherapy, or hormonal therapy) while on study.
- Requires concurrent treatment with an investigational agent, participation in another clinical trial, or any specifically prohibited medication while on study.
- Has a known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to 5-fluorouracil, folinic acid, oxaliplatin, or panitumumab.
- Other active malignancy
- Known alcohol abuse or drug addiction
- Incapability to give informed consent

Alter	18 Jahre und älter
Molekularer Marker	KRAS wt
Sponsor	Universitätsklinikum München
Förderer	AMGEN GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01384994 (primäres Register) EudraCT 2010-023671-26