KURZPROTOKOLL
RASH

Öffentlicher Titel	Gemcitabin plus Erlotinib bei Rash-positivem, metastasiertem Pankreaskarzinom und günstigen Risikofaktoren
Wissenschaftl. Titel	Phase II Studie zur Bestimmung der Effektivität von Gemcitabin plus Erlotinib bei Rash-positiven Patienten mit metastasiertem Pankreaskarzinom und günstigen Risikofaktoren
Kurztitel	RASH
Studienart	multizentrisch, prospektiv, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): Erstlinie
Ziele	- die 1-Jahresüberlebensrate von "good-risk" Patienten, die unter einer Behanldung mit Gemcitain/Erlotinib einen Rash entwickeln - ORR, DCR, PFS, OS - Verträglichkeit - Translationales Projekt
Einschlusskriterien	- Histologically (not cytologically) confirmed metastatic pancreatic adenocarcinoma (stage IV according to UICC, each T, each N, M1 according to TNM) - At least one measurable index lesion (CT or MRI) according to RECIST criteria (V 1.1) - ECOG PS 0 and 1 - Age 18-75 years - Serum bilirubin <=1,5x ULN (a placed biliary tract stent without concurrent cholangitis is not considered a contraindication) - Availability of tumour samples (no cytologic samples) - Written informed consent by the patient for collecting blood- and tumour-samples for translational research according to study protocol - Live expectancy of at least three months - Written informed consent - Negative pregnancy test in women with childbearing potential (to be performed within 7 days prior to treatment start) - Adequate kidney-, liver- and bone-marrow function: neutrophils >= 1500/µl, platelets >= 100.000/µ, and hemoglobin >= 8g/dl, liver transaminases<= 2,5x ULN, in case of liver metastases <= 5x ULN, serum creatinine <= 1,25x ULN, creatinine clearance >= 30 ml/min - Legal capacity of the patient - Option for constant long-term follow-up
Ausschlusskriterien	- Resectable pancreatic carcinoma - Locally advanced pancreatic cancer (non-resectable tumour without distant metastasis) - Previous palliative chemotherapy for metastatic or locally advanced, non-resectable pancreatic cancer - Previous palliative radiation or chemoradiation for locally advanced, non-resectable pancreatic cance - Radiation therapy within four weeks prior to study enrolment or radiation of indicator lesions - Adjuvant Chemotherapy or Radiochemotherapy for pancreatic cancer <= 6 months prior to study ernrolment - All previously occurred metastatic cancers or cured neoplasias diagnosed within the last 5 years before study enrolment

	- Major surgery within 2 weeks before study start - Chronic diarrhea - Known glucuronidation-deficiency (Gilbert´s syndrome) - Acute or subacute ileus or chronic inflammatory bowel disease - Preexisting polyneuropathy > Grade I according to NCI-CTCAE v.4.0 - Relevant comorbidities which might impair patient eligibility or safety for study participation like active infections, hepatic, renal or metabolic diseases - Clinically significant cardiovascular diseases within 12 months prior to study start (e.g. unstable angina pectoris, myocardial infarction, heart failure >= NYHA II, cardiac arrhythmias requiring treatment)
Alter	18 - 75 Jahre
Prüfzentren	**Krankenhaus Nordwest GmbH** (Geschlossen) Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Prof. Dr. med. Salah-Eddin Al-Batran Tel: 069 7601 4420 albatran@khnw.de
Sponsor	Universitätsklinikum München (Hauptsponsor)
Förderer	Universitätsklinikum München
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01729481 EudraCT 2011-005471-17