KURZPROTOKOLL
PANTHEON

Öffentlicher Titel	Phase II Studie zum Überleben nach sequenzieller Chemotherapie des metastasierten Bauchspeicheldrüsenkrebs
Wissenschaftl. Titel	A Health Service Research Study to Investigate Survival of Metastatic Pancreatic Cancer Patients After Sequential Chemotherapy: An AIO Phase II Cross Over Trial (PANTHEON)
Kurztitel	PANTHEON
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): Zweitlinie oder höher
Einschlusskriterien	- Written informed consent and any locally-required authorization (EU Data Privacy Directive in the EU) obtained from the subject prior to performing any protocol-related procedures, including screening evaluations - Age>= 18 years at time of study entry Unresectable adenocarcinoma of the pancreas previously treated in the palliative setting with gemcitabine and nabpaclitaxel (Abraxane®) - Adequately documented recurrence and disease status after/under 1st line (Best response, duration of treatment, time to progression, preexisting PNP and other side effects) - Radiologically confirmed disease progression during 1st-line therapy and measurable reference cancer site(s) as defined by RECIST1.1 - Randomization and start of 2nd-line treatment possible within 4 weeks after radiologically documented disease progression during 1st-line therapy - ECOG performance status 0-2 8. No prior radiotherapy - Adequate blood count, liver-enzymes, and renal function: - - Absolute neutrophil count (ANC) >= 1.5 x 10^9/L (> 1500 per mm³) - - Platelet count >= 100 x 10^9/L (>100,000 per mm³) - - AST (SGOT)/ALT (SGPT) < 2.5 x institutional upper limit of normal unless liver metastases are present, in which case it must be < 5x ULN - - Serum creatinine CL >= 60 mL/min calculations according to local standard - - Bilirubin < 3 ULN 10. Female subjects must either be of non-reproductive potential (ie, post-menopausal by history: 60 years old and no menses for >= 1 year without an alternative medical cause; OR history of hysterectomy, OR history of bilateral tubal ligation, OR history of bilateral oophorectomy) or must have a negative serum pregnancy test upon study entry - Subject is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits and examinations including follow up
Ausschlusskriterien	- Serious cardiovascular disease (eg, unstable coronary artery disease or myocardial infarction within 3 months prior to study start) - Preexisting polyneuropathy (PNP) >= grade 3 [National Cancer Institute Common Toxicity Criteria grade 3 or 4 sensory or motor neuropathy] - Prior or concurrent malignancy (other than pancreatic cancer) which either progresses or requires active treatment. Exceptions are: basal cell cancer of the skin - History of DPD deficiency - Morbus Gilbert - History of hypersensitivity to any of the study drugs or any of the constituents of the products - Medication that is known to interfere with any of the agents applied in the trial

	- Female subjects who are pregnant, breast-feeding or male or female patients of reproductive potential who are not employing an effective method of birth control (failure rate of less than 1% per year) - Any condition that, in the opinion of the investigator, would interfere with evaluation of study treatment or interpretation of patient safety or study results - Any medical condition that contraindicates dosing with any of the IMPs or constitutes a safety risk for the patient including but not limited to: - - chronic inflammatory bowel disease and/or bowel obstruction. - - active uncontrolled infection - - clinically significant bleeding or bleeding diathesis - - clinically significant stomatitis - - active ulceration of the gastrointestinal tract - Previous enrollment or randomization in the present study (does not include screening failure) - Patient who has been incarcerated or involuntarily institutionalized by court order or by the authorities § 40 Abs. 1 S. 3 Nr. 4 AMG - Patients who are unable to consent because they do not understand the nature, significance and implications of the clinical trial and therefore cannot form a rational intention in the light of the facts [§ 40 Abs. 1 S. 3 Nr. 3a AMG]
Alter	18 Jahre und älter
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Sponsor	AIO-Studien GmbH
Registrierung in anderen Studienregistern	EudraCT 2016-004640-11 ClinicalTrials.gov NCT03331640