KURZPROTOKOLL
AIO-PAK-0114 ALPACA

Öffentlicher Titel	Phase II Studie zur Induktionstherapie mit NAB-Paclitaxel/Gemcitabine als Erstlinienbehandlung von metastasiertem Pankreaskarzinom
Wissenschaftl. Titel	Induction Treatment With Nab-paclitaxel/Gemcitabine for First-line Treatment of Metastatic Pancreatic Cancer Followed by Either Alternating Application of Gemcitabine Monotherapy and Nab-paclitaxel/Gemcitabine or Continuing Application of Nab-paclitaxel/Gemcitabine: A Randomized Phase II Study
Kurztitel	AIO-PAK-0114 ALPACA
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): Erstlinie
Ziele	- Overall survival (OS) [Time Frame: After randomization until date of death or end of study wichever comes first. Assessed for up to 38.5 month] [Designated as safety issue: No] To estimate the treatment effect of alternating treatment cycles of gemcitabine monotherapy followed by nab-paclitaxel/gemcitabine relative to standard continuing nab-paclitaxel/gemcitabine treatment cycles in first-line treatment for metastatic pancreatic cancer in patients having received 3 cycles of induction therapy with standard nab-paclitaxel/gemcitabine.
Einschlusskriterien	- Adult patients (18 years of age) - Histologically or cytologically confirmed metastatic adenocarcinoma of the pancreas. Patients with islet cell neoplasms are excluded. - Karnofsky Perfomance Status (KPS) 70% - At least one unidimensionally measurable lesion as assessed by CT- scan or Magnetic resonance imaging (MRI) according to Response Evaluation Criteria In Solid Tumors (RECIST1.1), - Total bilirubin 1.5 x ULN (Upper Limit of Normal). Patients with a biliary stent may be included provided that bilirubin level after stent insertion decreased to 1.5 x ULN and there is no cholangitis. - Adequate renal, hepatic and bone marrow function, defined as Calculated creatinine clearance 30 mL/min according to CKD-EPI formula (Chronic kidney Disease Epidemiology Collaboration) AST/GOT and/or ALT/GPT 2.5 x ULN and 5.0 x ULN in case of liver metastasis Absolute neutrophil count (ANC) 1.5 x 10^9/L Haemoglobin 9 g/dL Platelets 100 x 100 x 10^9/L - Females of Childbearing Potential (FCBP) must have a negative serum pregnancy test within 7 days of the first application of study treatment and they must agree to undergo further pregnancy tests before randomization and at the end of treatment visit and - FCBP must either agree to use and be able to take effective contraceptive birth control measures (Pearl Index < 1) or agree to practice complete abstinence from heterosexual intercourse during the course of the study and for at least 1 month after last application of study treatment. A female subject is considered to be of childbearing potential unless she is age 50 years and naturally amenorrhoeic for 2 years, or unless she is surgically sterile. - Males must agree not to father a child during the course of the trial and for at least 6 months after last administration of study drugs. - Signed and dated informed consent before the start of any specific protocol procedures Patient's legal capacity to consent to study participation

Ausschlusskriterien

- Missing histological or cytological confirmation of metastatic adenocarcinoma of the pancreas Locally advanced pancreatic adenocarcinoma without metastases Any previous radiotherapy, surgery, chemotherapy or investigational therapy for the treatment of metastatic disease. (Prior adjuvant chemotherapy with gemcitabine or fluoropyrimidine in curative intent is allowed if terminated more than 6 months before first application of study treatment. Previous palliative radiotherapy of bonemetastases for alleviation of pain is permitted provided that irradiated bone metastases are no target lesions.) Known brain metastase/brain metastases. Brain imaging is required in symptomatic patients to rule out brain metastases, but is not required in asymptomatic patients.
- Pre-existing peripheral neuropathy grade 2 according to CTCAE version 4 (Common Terminology Criteria for Adverse Events)
- • Medical history of interstitial lung disease (ILD) or pulmonary fibrosis
- Patients with high cardiovascular risk, including, but not limited to, recent coronary stenting or myocardial infarction in the past year.
- Uncontrolled severe illness or medical condition (including uncontrolled diabetes mellitus)
- Any other severe concomitant disease or disorder, which could influence patient's ability to participate in the study and his/her safety during the study or interfere with interpretation of study results e.g. severe hepatic, renal, pulmonary, metabolic, or psychiatric disorders Previous or concurrent tumor other than underlying tumor disease (pancreatic cancer) with the exception of cervical cancer in situ, adequately treated basal cell carcinoma or squamous cell carcinoma of the skin, superficial bladder tumors (Ta, Tis, and T1) or any curatively treated tumors > 5 years prior to enrolment Hypersensitivity against nab-paclitaxel, gemcitabine, or any excipients of these drugs
- Continuing abuse of alcohol, drugs, or medical drugs
- Pregnant females, breast feeding females or females of childbearing potential unable to perform adequate contraceptive measures or practice complete abstinence from heterosexual intercourse
- Participation in any other clinical trial or treatment with any experimental drug within 28 days before enrolment to the study or during study participation until the end of treatment visit.

Alter 18 Jahre und älter

Fallzahl 325

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