KURZPROTOKOLL
AIO-PAK-0313 (NEONAX)

Öffentlicher Titel	Nab-Paclitaxel plus Gemcitabine bei resektablem Pankreaskarzinom
Wissenschaftl. Titel	Neoadjuvant plus adjuvant or only adjuvant nab-Paclitaxel plus Gemcitabine for resectable pancreatic cancer - The AIO-NEONAX trial (AIO-PAK-0313). A prospective, randomized, controlled, phase II study of the AIO Pancreatic Cancer Group
Kurztitel	AIO-PAK-0313 (NEONAX)
Studienart	prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, kontrolliert, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): neoadjuvant Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): adjuvant
Einschlusskriterien	- Histologically or cytological confirmed clearly resectable ductal adenocarcinoma of the pancreas (PDAC) <= cT3 with no prior tumor specific treatment. - No evidence of metastases to distant organs (e.g. liver, peritoneum, lung). - Resectable tumor: Determination of resectability based on spiral CT scans with both oral and i.v. contrast enhancement or on MRI using a recent consensus definition (Resectability: Clear fat planes around the celiac artery, hepatic artery and superior mesenteric artery).1,2 - ECOG performance status 0 or 1 - Creatinine clearance >= 30 ml/min - Serum total bilirubin level <= 2.5 x ULN (not necessary for enrollment or randomization, but before start of neoadjuvant chemotherapy) - Transaminases (ALT and AST) <= 2.5 x ULN (not necessary for enrollment or randomization, but before start of neoadjuvant chemotherapy) - In case of biliary obstruction, biliary decompression is required if the patient was randomized to recieve neoadjuvant Chemotherapy (arm A). - White blood cell count >= 3.5 x 10^6/ml, neutrophil granulocytes count >= 1,5 x 10^6/ml, platelet count >= 100 x 10^6/ml - Signed informed consent incl. participation in translational research - Age >= 18 years
Ausschlusskriterien	- Borderline resectable PDAC by radiologic criteria - Papillary cancer - Neuroendocrine Cancer - Tumor specific pre-treatment - Local recurrence - Peritoneal or other distant metastases - Radiographic evidence of severe portal hypertension/cavernous transformation - Infiltration of extrapancreatic organs (except duodenum) - Ascites - Gastric outlet obstruction - Global respiratory insufficiency requiring oxygen supplementation - Chronic infectious diseases, immune deficiency syndromes - Premalignant hematologic disorders, e.g. myelodysplastic syndrome - Disability to understand and sign written informed consent document - Past or current history of malignancies except for the indication under this study and curatively treated: (a) Basal and squamous cell carcinoma of the skin; (b) In-situ carcinoma of the cervix; (c) Other malignant disease without recurrence after at least 2 years of follow-up

- Clinically significant cardiovascular disease in (incl. myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) 6 months before enrollment
- Clinically relevant or history of interstitial lung disease, e.g. non-infectious pneumonitis or pulmonary fibrosis or evidence of interstitial lung disease on baseline chest CT scan
- History of or evidence upon physical examination of CNS disease unless adequately treated (e. g. primary brian tumor, seizure not controlled with standard medical therapy or history of stroke).
- Pre-existing neuropathy > grade 1 (NCI CTCAE), except for loss of tendon reflex
- Allogeneic transplantation requiring immunosuppressive therapy or other major immunosuppressive therapy
- Severe non-healing wounds, ulcers or bone fractions
- Evidence of bleeding diathesis or coagulopathy
- Patients not receiving therapeutic anticoagulation must have an INR < 1.5 ULN and PTT < 1.5 ULN within 28 days prior to randomization. The use of full dose anticoagulants is allowed as long as the INR or PTT is within therapeutic limits (according to the medical standard in the institution) and the patient has been on a stable dose for anticoagulants for at least two weeks at the time of randomization
- Major surgical procedure, except open biopsy, nor significant traumatic injury within 28 days prior randomization, or anticipation of the need for major surgical procedure during the course of the study except for surgery for pancreatic cancer with curative intent and central venous line placement for chemotherapy administration.
- Pregnancy or breastfeeding women.
- Subjects with known allergies to the study drugs or to any of its excipients.
- Current or recent (within the 28 days prior randomization) treatment of another investigational drug or participation in another investigational study.
- Any psychological, familial, sociological or geographical condition potentially compromising compliance with the study protocol and the follow-up schedule; those conditions should be discussed with the patient prior to registration in the trial

Alter

18 Jahre und älter

Prüfzentren

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