First-line Treatment of Metastatic Pancreatic Cancer With Nab-paclitaxel and Gemcitabine (ALPACA)

This study is currently recruiting participants. (see Contacts and Locations)

Verified December 2016 by AIO-Studien-gGmbH

Sponsor:
AIO-Studien-gGmbH

Collaborators:
ClinAssess GmbH
Celgene Corporation

Information provided by (Responsible Party):
AIO-Studien-gGmbH

ClinicalTrials.gov Identifier:
NCT02564146

First received: September 29, 2015
Last updated: December 19, 2016
Last verified: December 2016
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

ALPACA is an interventional, multicentre, open-label, randomized active-controlled phase II trial with two arms.

To estimate the treatment effect on overall survival, feasibility, efficacy and safety of alternating treatment cycles of gemcitabine monotherapy followed by nab-paclitaxel/gemcitabine relative to standard continuing nab-paclitaxel/gemcitabine cycles in first-line treatment for metastatic pancreatic cancer in patients having received 3 cycles of induction therapy with standard nab-paclitaxel/gemcitabine.

Condition	Intervention	Phase
Metastatic Pancreatic Cancer Adenocarcinoma of the Pancreas	Drug: nab-paclitaxel and gemcitabine Drug: gemcitabine mono and nab-paclitaxel and gemcitabine	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: 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

Resource links provided by NLM:

MedlinePlus related topics: Pancreatic Cancer

Drug Information available for: Paclitaxel Gemcitabine Gemcitabine hydrochloride

U.S. FDA Resources

Further study details as provided by AIO-Studien-gGmbH:

Primary Outcome Measures:

- 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]

  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.

Secondary Outcome Measures:

- Overall survival (OS) [Time Frame: 3.5 month]
  During induction phase.
- Overall survival (OS) [Time Frame: 42 month]
  Determined from first application of induction treatment.
- Progression-free survival (PFS) [Time Frame: 3.5 month]
  During induction phase.
- Progression-free survival (PFS) [Time Frame: Assessed for up to 38.5 month]
  As time from randomization to objective tumor progression or death from any cause.
- Progression-free survival (PFS) [Time Frame: Assessed for up to 42 month]
  As time from randomization to objective tumor progression or death from any cause.
- Overall response rate (ORR) [Time Frame: Assessed for up to 42 month]
  According to RECISTv1.1 determined from first application of induction treatment.
- Overall response rate (ORR) [Time Frame: Assessed for up to 3.5 month]
  During induction phase.
- Disease control rate (DCR) [Time Frame: Assessed for up to 42 month]
  According to RECISTv1.1 determined from first application of induction treatment.
- Disease control rate (DCR) [Time Frame: Assessed for up to 3.5 month]
  During induction phase.
- Quality of life QLQ-C30 [Time Frame: Assessed for up to 3.5 month]
  During induction phase.
- Quality of life QLQ-C30 [Time Frame: Assessed for up to 8 month]
  As determined with EORTC QLQ-C30 determined from randomization.
- Adverse Events (AE) [Time Frame: Assessed for up to 11.5 month]
  Type, incidence, and severity according to NCI CTCAE version 4 with explicit consideration of any neurotoxicity.
- Adverse Events (AE) [Time Frame: Assessed for up to 3.5 month]
  Type, incidence, and severity according to NCI CTCAE version 4 with explicit consideration of any neurotoxicity during induction phase.
- Time of treatment without toxicity [Time Frame: Assessed for up to 11.5 month]
  Duration of treatment without toxicity leading to permanent discontinuation during induction and randomized phase.
- Time of treatment without toxicity [Time Frame: Assessed for up to 3.5 month]
  Duration of treatment during induction phase.
- Neurotoxicity Assessment FACT taxane score [Time Frame: Assessed for up to 11.5 month]
  Functional assessment of neurotoxicity (with FACT taxane score) during induction and randomized phase.
- Neurotoxicity Assessment FACT taxane score [Time Frame: Assessed for up to 3.5 month]
  Functional assessment of neurotoxicity (with FACT taxane score) during induction phase.

Estimated Enrollment:	325
Study Start Date:	December 2016
Estimated Study Completion Date:	June 2019
Estimated Primary Completion Date:	January 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: nab-paclitaxel and gemcitabine (A) Induction treatment: 3 cycles nab-paclitaxel and gemcitabine Continuous treatment after randomization: Continuing application of nab-paclitaxel and gemcitabine treatment cycles	Drug: nab-paclitaxel and gemcitabine Induction treatment: 3 cycles nab-paclitaxel and gemcitabine 125 mg/m^2, IV infusion over 30 minutes, followed by gemcitabine 1000 mg/m^2 as a 30-minute IV infusion; D1, D8, D15 of each 28-day cycle. Continouous treatment after randomization: Continuing application of nab-paclitaxel and gemcitabine treatment cycles until progression or unacceptable toxicity. Duration of each cycle is 28 days nab-paclitaxel 125 mg/m^2, IV infusion over 30 minutes, followed by gemcitabine 1000 mg/m^2 as a 30-minute IV infusion; D1, D8, D15 of each 28-day cycle.
Experimental: gemcitabine monotherapy and nab-paclitaxel and gemcitabine (B) Induction treatment: 3 cycles nab-paclitaxel and gemcitabine Continuous treatment after randomization: alternating application of gemcitabine monotherapy and nab-paclitaxel and gemcitabine treatment cycles	Drug: nab-paclitaxel and gemcitabine Induction treatment: 3 cycles nab-paclitaxel and gemcitabine 125 mg/m^2, IV infusion over 30 minutes, followed by gemcitabine 1000 mg/m^2 as a 30-minute IV infusion; D1, D8, D15 of each 28-day cycle. Continouous treatment after randomization: Continuing application of nab-paclitaxel and gemcitabine treatment cycles until progression or unacceptable toxicity. Duration of each cycle is 28 days nab-paclitaxel 125 mg/m^2, IV infusion over 30 minutes, followed by gemcitabine 1000 mg/m^2 as a 30-minute IV infusion; D1, D8, D15 of each 28-day cycle. Drug: gemcitabine mono and nab-paclitaxel and gemcitabine Induction treatment: 3 cycles nab-paclitaxel and gemcitabine 125 mg/m^2, IV infusion over 30 minutes, followed by gemcitabine 1000 mg/m^2 as a 30-minute IV infusion; D1, D8, D15 of each 28-day cycle. Continouous treatment after randomization: Alternating application of gemcitabine monotherapy and nab-paclitaxel and gemcitabine treatment cycles until progression or unacceptable toxicity, starting with a treatment cycle of gemcitabine monotherapy. Duration of each cycle irrespective of treatment cycle with gemcitabine monotherapy or treatment with nab-paclitaxel/gemcitabine is 28 days. Gemcitabine monotherapy treatment cycle: Gemcitabine 1000 mg/m^2 as a 30-minute IV infusion; D1, D8, D15 of each 28-day cycle. Nab-paclitaxel and gemcitabine treatment cycle: Nab-paclitaxel 125 mg/m^2, IV infusion over 30 minutes, followed by gemcitabine 1000 mg/m^2 as a 30-minute IV infusion; D1, D8, D15 of each 28-day cycle.

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- 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

Exclusion Criteria:

- 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.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02564146

Contacts

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Locations

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Sponsors and Collaborators

AIO-Studien-gGmbH

ClinAssess GmbH

Celgene Corporation

Investigators

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More Information

Responsible Party:	AIO-Studien-gGmbH
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Individual Participant Data

Plan to Share IPD: No

Additional relevant MeSH terms:

Adenocarcinoma
Pancreatic Neoplasms
Carcinoma
Neoplasms, Glandular and Epithelial
Neoplasms by Histologic Type
Neoplasms
Digestive System Neoplasms
Neoplasms by Site
Endocrine Gland Neoplasms
Digestive System Diseases
Pancreatic Diseases
Endocrine System Diseases
Paclitaxel
Gemcitabine
Albumin-Bound Paclitaxel
Antineoplastic Agents, Phytogenic
Antineoplastic Agents
Tubulin Modulators
Antimitotic Agents
Mitosis Modulators
Molecular Mechanisms of Pharmacological Action
Antimetabolites, Antineoplastic
Antimetabolites
Antiviral Agents
Anti-Infective Agents
Enzyme Inhibitors
Immunosuppressive Agents
Immunologic Factors
Physiological Effects of Drugs

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