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A randomised multicentre clinical phase IIIb trial for patients suffering from pancreatic adenocarcinoma receiving defined second or higher line chemotherapy and additionally parenteral nutrition (study arm A) or best supportive nutritional care (study arm B)

Submission date 20/11/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/12/2008	**Overall study status** Completed	
Last Edited 19/05/2022	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2008-004696-22

Protocol serial number
NCT (National Centre for Tumour Diseases): 2008-11-03-1018

Study information

Scientific Title
An open label randomised multicentre phase IIIb trial comparing parenteral substitution versus best supportive nutritional care in subjects with pancreatic adenocarcinoma receiving 5-fluorouracil (5-FU) plus oxaliplatin as second or higher line chemotherapy regarding clinical benefit

Acronym
PANUSCO

Study objectives
Nutritional intervention (NI) will prevent loss in the health-related quality of life (HQoL) (change from baseline of at least ten points in European Organisation for Research and Treatment of Cancer [EORTC] Quality of Life Questionnaire (QLQ)-C30, functional domain total score). This effect is thought to be more pronounced in subjects with a performance status (PS) of Eastern Cooperative Oncology Group (ECOG) greater than or equal to 2.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, controlled, open-label, phase IIIb, multicentre, two-armed parallel clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Advanced pancreatic adenocarcinoma

Interventions
The clinical trial PANUSCO is subdivided in two different study arms. All patients receive a defined chemotherapy as described below:

5-Fluorouracil (5-FU) 2000 mg/m^2 intravenously (IV) (24-hour)/folinic acid (FA) 200 mg/m^2 IV (30 min) will be administered weekly over four weeks with additional oxaliplatin 85 mg/m^2 IV (2-hour) on days 8 and 22. Therapy will be interrupted between days 23 to 42. The next cycle will be started on day 43. Therapy will be given until a study withdrawal criterion (disease progression, unacceptable toxicity or subject's consent withdrawal) is met.

Study arm A: patients receive additional parenteral nutrition -
The subjects in the experimental group receive nutritional consultation, recommendation and parenteral supplementation (overnight with SMOFKabiven®, Omegaven®, Frekavit fat-soluble®, Frekavit water-soluble novum® and Tracitrans plus®). PN will be given continuously on six days a week. PN will be discontinued during chemotherapy.

Study arm B: patients receive best supportive nutritional care -
Subjects in the control group receive best supportive nutritional care (BSNC). Every kind of enteral nutrition and oral supplementation is allowed. Subjects will be requested to avoid oral intake of omega-three-fatty acids.

Total duration of treatment for both study arms is four months including three months of chemotherapy for each subject. Patients will be followed-up monthly via phone after treatment.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
5-Fluorouracil (5-FU), folinic acid (FA), oxaliplatin, SMOFKabiven®, Omegaven®, Frekavit fat-soluble®, Frekavit water-soluble novum® and Tracitrans plus®

Primary outcome(s)
The comparison of the treatment groups with respect to event-free survival (EFS). EFS is defined as the time from randomisation until time to development of an event defined as either an impairment (change from baseline of at least ten points in EORTC QLQ-C30, functional domain total score) or withdrawal due to fulfilling the stopping criteria or death from any cause (whichever occurs first).

Key secondary outcome(s))
1. Comparison of the treatment groups with respect to tumour-cachexia
2. Objective response rate (ORR)
3. Time to progression (TTP)
4. Progression free survival (PFS)
5. Overall survival (OS)
6. Toxicity

Time from randomisation until time point when stopping criteria are met, definition and evaluation of a scoring system identifying subject groups who will benefit from second line chemotherapy and/or parenteral nutrition (PN).

Completion date
31/03/2011

Eligibility

Key inclusion criteria

1. Written informed consent
2. Histologically confirmed advanced pancreatic adenocarcinoma
3. At least one previous chemotherapy (gemcitabine-based)
4. Greater than or equal to 18 years old, either sex
5. Body weight greater than or equal to 50 kg and less than or equal to 95 kg
6. Body mass index (BMI) greater than or equal to 19 kg/m^2
7. Negative pregnancy test (females of childbearing potential)
8. Willingness to perform double-barrier contraception during study
9. Life expectancy greater than 3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Major surgery less than 4 weeks prior to enrolment
2. Weight loss greater than 2% within the last seven days or caloric intake less than or equal to 500 kcal expected within the next five days
3. Prognostic and Inflammatory Nutritional Index (PINI) greater than 10
4. Pregnancy or breastfeeding
5. Greater than 4 weeks of parenteral nutrition within the last 6 months
6. Parenteral nutrition less than 4 weeks of enrolment
7. Vulnerable populations (e.g. subjects incapable of giving consent personally)
8. Subject selection conflicts with warnings, precautions and contraindications stated for any investigational product

Subjects will be stratified by ECOG PS (stratum 1: PS less than 2, stratum 2: PS greater than or equal to 2).

Date of first enrolment
01/04/2009

Date of final enrolment
31/03/2011

Locations

Countries of recruitment

Germany

Study participating centre
Universitätsklinikum Heidelberg
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Sponsor information

Organisation
University of Heidelberg (Germany)

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
University/education

Funder Name
University of Heidelberg (Germany)

Alternative Name(s)
University of Heidelberg, Ruprecht-Karls-Universität Heidelberg

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/11/2009		Yes	No
Basic results		04/11/2020	19/05/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes