

# 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)

<b>Submission date</b> 20/11/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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**

Intentional

**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<sup>2</sup> intravenously (IV) (24-hour)/folinic acid (FA) 200 mg/m<sup>2</sup> IV (30 min) will be administered weekly over four weeks with additional oxaliplatin 85 mg/m<sup>2</sup> 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<sup>2</sup>
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**  
Heidelberg  
Germany  
69120

## 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?
<a href="#">Protocol article</a>	protocol	27/11/2009		Yes	No
<a href="#">Basic results</a>		04/11/2020	19/05/2022	No	No