

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/12/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/05/2022	Condition category 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

EudraCT/CTIS number

2008-004696-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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/m² intravenously (IV) (24-hour)/folinic acid (FA) 200 mg/m² IV (30 min) will be administered weekly over four weeks with additional oxaliplatin 85 mg/m² 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 measure

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).

Secondary outcome measures

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).

Overall study start date

01/04/2009

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/m²
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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

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)

Sponsor details

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irmtraut.guerkan@med.uni-heidelberg.de

Sponsor type

University/education

Website

<http://www.uni-heidelberg.de>

ROR

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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