Palliative pylorus-preserving pancreatic head resection and postoperative chemotherapy versus primary chemotherapy alone for patients with advanced carcinoma of the pancreatic head

Submission date	Recruitment status	Prospectively registered
24/05/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
02/07/2007	Completed	Results
Last Edited	Condition category	Individual participant data
21/09/2007	Cancer	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2002

Study information

Scientific Title

Acronym

Palliative Pylorus-Preserving Pancreatododenectomy (Palliative PPPD)

Study objectives

Survival and quality of life after palliative pylorus-preserving pancreatoduodenectomy and postoperative chemotherapy with Gemzar® is increased when compared to Gemzar® chemotherapy alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from local Institutional Review Board (IRB) (Ethics Board of the Charité, Medical Faculty, Humboldt University, now known as the Ethics Committee State Berlin) on the 30th August 2002.

Study design

Open prospective randomised study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pancreatic head carcinoma

Interventions

Group 1: standard pylorus-preserving pancreatic head resection with regional lymphadenectomy (this is an internationally well accepted surgical procedure) and after completion of wound healing (up to four weeks postoperative) standard chemotherapy with gemcitabine is started (see below). The chemotherapy is the same as in group 2.

Group 2: standard gemcitabine chemotherapy alone: 1000 mg/m^2 body surface once per week

for four weeks with a one-week break, i.e., three weeks treatment and one week free. This is an internationally accepted standard for gemcitabine in advanced pancreatic carcinoma treatment.

Drugs will be administered on an out patient basis intravenously (i.v.) through a port system. Follow up period is one year.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gemcitabine (Gemzar®)

Primary outcome measure

Survival, measured after 3, 6 and 12 months

Secondary outcome measures

- 1. Quality of life, measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) and the EORTC Quality of Life Questionnaire for Pancreatic cancer (QLQ PAN26). This will be measured after 3, 6 and 12 months
- 2. Surgical complications, measured after 3, 6 and 12 months
- 3. Toxicity of chemotherapy, measured after 3, 6 and 12 months

Overall study start date

15/09/2003

Completion date

31/12/2009

Eligibility

Key inclusion criteria

Medical centres experienced in surgical and medical care of patients with pancreatic head carcinoma.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

15 to 20 patients

Key exclusion criteria

No exclusion criteria.

Date of first enrolment

15/09/2003

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Germany

Study participating centre Department of Surgery

Berlin Germany 13589

Sponsor information

Organisation

Humboldt University Berlin (Germany)

Sponsor details

Department of General-, Viszeral- and Transplantational-Surgery Charite Universitaetsmedizin Berlin Campus Virchow-Klinikum Augustenburger Platz 1 Berlin Germany 13353

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Sponsor type

University/education

Website

http://www.charite.de/start/

ROR

https://ror.org/01hcx6992

Funder(s)

Funder type

University/education

Funder Name

Humboldt University Berlin (Germany) - Department of Surgery at Charité Campus Virchow Clinic

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration