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

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

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

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
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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