ISRCTN78805636 https://doi.org/10.1186/ISRCTN78805636

Preoperative chemoradiation in locally resectable adenocarcinoma of pancreatic head without metastasis

Submission date	Recruitment status	[_] Prospectively registered
17/01/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/04/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/09/2014	Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.chirurgie.med.uni-erlangen.de/frames/f_forschung.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00335543

Secondary identifying numbers
70-3046-Ho 2

Study information

Scientific Title

Study objectives
Aim of the study is to investigate if preoperative chemoradiation is better than immediate surgery regarding median survival for patients with local resectable adenocarcinoma of the pancreatic head without metastasis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local medical ethics committee (Ethik-Kommission der Medizinischen Fakultat der Friedrich-Alexander-Universitat Erlangen-Nurnberg) on 28/12/2001 (followed by further letters: 21/01/2002, 19/08/2003, 27/07/2004, 11/07/2005).

Study design
Randomised controlled open multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Locally resectable adenocarcinoma of pancreatic head

Interventions
Treatment A: Operation (Whipple operation, standardised lymph node dissection)
Treatment B: Neoadjuvant chemoradiotherapy with gemcitabine and cisplatin followed by operation (same as treatment A) six weeks later: radiotherapy with single doses of 1.8 Gy on day one to five for five weeks (total dose of 50.4 Gy for tumour and surrounding lymph nodes) and

three further doses only for the tumour (total dose 55.8 Gy). Gemcitabine intravenously (iv) 300 mg/m^2 body surface area and cisplatin iv 30 mg/m^2 body surface area on day one, eight, 22, and 29.

Amendment July 11 2005: All resected patients should now receive adjuvant chemotherapy for example gemcitabine 1000 mg/m^2 on day one, eight, 15 (one cycle day 1-28) for six months. NB: it is not the aim of the study to investigate the need of adjuvant chemotherapy.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Cisplatin, gemcitabine

Primary outcome measure
Median survival of patients from time of randomisation.

Secondary outcome measures
1. Three year survival rate
2. R0-resection rate
3. Rate of medium and high toxicity events (common toxicity criteria)
4. Rate of complete and incomplete remission of the tumour in radiographic imaging studies
5. Rate of different regression gradings in resected tumour specimens
6. Quality of life before/during and after therapy

Overall study start date
23/06/2003

Completion date
30/06/2009

Eligibility

Key inclusion criteria
1. Adenocarcinoma of pancreatic head, histologically or cytologically proven, resectable as assessed by computed tomography (CT)-scan (major vessels [V. portae, confluence of V. mesenterica and lienalis, A. mes. sup., Truncus coeliacus, A. lienalis, A. hepatica, V. mes. sup.] maximally enclosed up to 180° by the tumour)
2. No infiltration of extrapancreatic organs (exception: duodenum)
3. Only one peripancreatic lymph node (LN) greater than 1 cm on CT-scan (amendment July 11 2005 - this criterion was removed)
4. No metastasis
5. No peritoneal carcinosis (laparoscopy facultative)
6. Age between 18 and 75 years (amendment July 11 2005 - aged 18 or over)
7. Good performance (Karnofsky-index greater than 60)
8. No previous treatment for carcinoma of pancreas
9. No previous malignant disease (exception: non-melanomatous skin tumour, carcinoma in situ

of cervix uteri, malignant disease in complete remission treated only surgically at least ten years ago)
10. No participation in other clinical trial in the last three months before randomisation
11. No liver cirrhosis (Quick greater than 70%, thrombocytes greater than 100,000 mm^3)
12. Serum-creatinine less than 1.5 mg/dl; creatinine-clearance greater than 70 ml/min
14. No severe cardiopulmonal disease or any disease which renders the patient not suitable for one treatment option
15. No human immunodeficiency virus (HIV)-infection
16. No lack of judiciousness
17. Written informed consent by the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
254

Key exclusion criteria
1. Ampullary carcinoma (tumours origination from the ampulla, the papilla or at the junction of the ampulla and the papilla)
2. Carcinoma of the pancreatic corpus or tail (tumours between the left edge of the superior mesenteric vine and the left edge of the aorta respectively between the left edge of the aorta and the splenic hilum)
3. Non-ductal adenocarcinoma of the pancreas (e.g. cystadenocarcinoma, neuroendocrine tumours, etc.)
4. Pregnancy or insufficient contraception
5. Aged less than 18 years
6. Karnofsky performance status less than 70
7. Doubtful understanding or contractual capacity of the patient

Date of first enrolment
23/06/2003

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Austria

Germany

Switzerland

Study participating centre
Director
Erlangen
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91054

Sponsor information

Organisation
Friedrich-Alexander University Erlangen-Nuremberg - Medical Faculty (Germany)

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Sponsor type
University/education

ROR
https://ror.org/00f7hpc57

Funder(s)

Funder type
Charity

Funder Name
German Cancer Aid (Deutsche Krebshilfe) (Germany) (ref: 70-3046-Ho 2)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/03/2007		Yes	No
Results article	results	01/07/2008		Yes	No
Results article	results	01/01/2015		Yes	No