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Adjuvant chemotherapy with gemcitabine versus observation in patients undergoing curative-intent resection of pancreatic cancer: a multicentre randomised controlled trial

Submission date 12/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/12/2006	**Overall study status** Completed	
Last Edited 02/07/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
German Tumour Study Registry (Deutsches KrebsStudienRegister) ID No.: 200

Study information

Scientific Title

Adjuvant chemotherapy with gemcitabine versus observation in patients undergoing curative-intent resection of pancreatic cancer: a multicentre randomised controlled trial

Acronym
CONKO-001

Study objectives
To test the hypothesis that adjuvant chemotherapy with gemcitabine administered after complete resection of pancreatic cancer improves disease-free survival (DFS) by six months or more.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charite - Universitätsmedizin Berlin Ethik-Kommission, 28/11/1997, ref: 143/97

Study design
Open multicentre randomised controlled phase III trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pancreatic cancer

Interventions
Patients were randomised, with stratification for resection, T and nodal status, to receive adjuvant chemotherapy with six cycles of gemcitabine day one, eight and 15 every four weeks (Arm A) or observation (Arm B).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Gemcitabine

Primary outcome(s)
Disease-free survival (DFS)

Key secondary outcome(s))
1. Overall survival (OS)
2. Toxicity
3. Quality of life

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Histologically proven resected pancreatic carcinoma
2. Standard operation
3. No measurable disease
4. No prior chemo- or radiotherapy
5. No active infection
6. Karnofsky performance status minimum 50%
7. Adequate haematologic, renal and hepatic function
8. Cancer antigen 19-9 (CA 19-9), carcinoembryonic antigen (CEA) less than 2.5 x upper limit of normal (ULN)
9. Start with adjuvant therapy within six weeks after resection
10. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Active infection
2. Impaired coagulation (international normalised ratio [INR] and/or activated partial thromboplastin time [aPPT] more than 1.5 x ULN)
3. Transaminases more than 3 x ULN
4. Serum creatinine more than 1.5 x ULN
5. Postoperative tumour markers (CEA/CA19-9) more than 2.5 x ULN
6. History of another malignant disease other than carcinoma in situ of the uterine cervix or adequately treated basal cell carcinoma of the skin
7. Pregnant or breastfeeding women

Date of first enrolment
01/07/1998

Date of final enrolment
31/12/2004

Locations

Countries of recruitment

Austria

Germany

Study participating centre
Augustenburger Platz 1
Berlin
Germany
13344

Sponsor information

Organisation
Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Industry

Funder Name
Lilly Deutschland GmbH (Germany)

Results and Publications

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?
Results article	results	17/01/2007		Yes	No
Results article	results	09/10/2013		Yes	No
	results				

Results article		01/05/2014		Yes	No
Results article	results	11/11/2014		Yes	No
Results article	results	01/08/2015		Yes	No
Results article	results	01/05/2018	02/07/2019	Yes	No