

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
Registration date 21/12/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/07/2019	Condition category Cancer	☐ 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

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

Primary study design

Interventional

Study design

Open multicentre randomised controlled phase III trial

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 - Universitätsmedizin 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