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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

Contact name
Dr Helmut Oettle

Contact details
Augustenburger Platz 1
Berlin
Germany
13344
-
helmut.oettle@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 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 measure
Disease-free survival (DFS)

Secondary outcome measures
1. Overall survival (OS)
2. Toxicity
3. Quality of life

Overall study start date
01/07/1998

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

Age group
Not Specified

Sex
Both

Target number of participants
368

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)

Sponsor details
Augustenburger Platz 1
Berlin
Germany
13344
-
lars.roll@charite.de

Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Industry

Funder Name
Lilly Deutschland GmbH (Germany)

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