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Oxaliplatin/folinic acid/5-fluorouracil (24-hour) (OFF) plus best supportive care versus best supportive care alone (BSC) in second-line therapy of gemcitabine-refractory advanced pancreatic cancer

Submission date 24/07/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/12/2007	**Overall study status** Completed	
Last Edited 08/04/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.conko-studien.de/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00786058

Secondary identifying numbers
German Tumour Study Registry (Deutsches KrebsStudienRegister) ID No.: 427; CONKO-003

Study information

Scientific Title
Oxaliplatin/folinic acid/5-fluorouracil (24-hour) (OFF) plus best supportive care versus best supportive care alone (BSC) in second-line therapy of gemcitabine-refractory advanced pancreatic cancer

Study objectives
Study hypothesis:
To test the hypothesis that second-line chemotherapy with OFF improves overall survival compared to best supportive care alone.

Amendment 1:
To test the hypothesis that second-line chemotherapy with OFF improves overall survival compared to folinic acid/5-fluorouracil (24-hour) and best supportive care alone (FF).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Ethikkommission der Charite Universitatsmedizin Berlin on the 14th October 2002 (ref: 192/2002); amendment 1 approved on 12th December 2003.

Study design
Prospective, 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
After stratification for duration of first line therapy, Karnofsky Performance Status (KPS) and tumour stage, patients were randomised and treated with 5-fluorouracil (FU) 2 g/m^2 (24-hour) /folinic acid (FA) 200 mg/m^2 (FF) on days 1, 8, 15 and 22 with or without oxaliplatin 85 mg/m^2 (2-hour) on days 8 and 22. Therapy paused on days 23 to 42.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Oxaliplatin, folinic acid, 5-fluorouracil

Primary outcome measure
Overall survival, progression free survival: Kaplan Meyer Plot (current version of SPSS).

Secondary outcome measures
1. Rate of remission: description with tabulations, as percentage of the two treatment groups, duration of remission
2. Toxicity: NCI Common Toxicity Criteria (CTC) grade differentation, description with tabulations
3. Quality of life: tabulation descriptions, assesment with box-plot (current version of SPSS)

Overall study start date
01/01/2004

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Histologically or cytologically proven advanced pancreatic cancer after confirmed failure of treatment with gemcitabine
2. No more than three weeks between confirmed failure of treatment with gemcitabine and start of second-line therapy
3. Karnofsky performance status greater than 70%
4. Measurable disease of more than 15 x 15 mm per computed tomography (CT) or magnetic resonance (MR) scan
5. Leucocytes greater than 3.5 x 10^9/L, platelets greater than 100 x 10^9/L
6. Written informed consent
7. Age of 18 years or more
8. Sufficient contraception up to three months after the end of therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
165

Total final enrolment
46

Key exclusion criteria
1. Active infection (as decided by physician)
2. Pregnant or breastfeeding women
3. Psychiatric disorders
4. Heavy disorders, contradictory with study (as decided by physician)
5. Heavy complications of the tumour, requiring an acute therapy
6. Heavy cardiac disorders
7. Peripheral, sensory and/or motor neuropathy (greater than II° - grade of sensoric/motoric toxicity regarding National Cancer Institute [NCI] criteria)
8. Hyperesthesia against study medication or related drugs
9. Patients with renal failure (creatinine clearance less than 30 ml/min)

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Germany

Study participating centre
Augustenburger Platz 1
Berlin
Germany
13344

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

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Sponsor type
University/education

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ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Industry

Funder Name
Amgen GmbH (Germany)

Funder Name
Medac (Germany)

Funder Name
Ribosepharm GmbH (Germany)

Funder Name
Sanofi-Aventis 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		01/06/2005	08/04/2021	Yes	No
Results article		10/08/2014	08/04/2021	Yes	No