

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
Registration date 21/12/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/04/2021	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

ClinicalTrials.gov (NCT)
NCT00786058

Protocol serial number
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 Universitätsmedizin Berlin on the 14th October 2002 (ref: 192/2002); amendment 1 approved on 12th December 2003.

Primary study design

Interventional

Study design

Prospective, open, multicentre, randomised, controlled phase III trial

Study type(s)

Treatment

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/m² (24-hour) /folinic acid (FA) 200 mg/m² (FF) on days 1, 8, 15 and 22 with or without oxaliplatin 85 mg/m² (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(s)

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

Key secondary outcome(s)

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 differentiation, description with tabulations
3. Quality of life: tabulation descriptions, assesment with box-plot (current version of SPSS)

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 $3.5 \times 10^9/L$, platelets greater than $100 \times 10^9/L$
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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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	Study website	01/06/2005	08/04/2021	Yes	No
Results article		10/08/2014	08/04/2021	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes