

A Prospective, Randomised trial Of Simultaneous Pancreatic cancer treatment with Enoxaparin and ChemoTherapy

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 27/10/2022	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.: 428; CONKO-004

Study information

Scientific Title

A Prospective, Randomised trial Of Simultaneous Pancreatic cancer treatment with Enoxaparin and ChemoTherapy

Acronym
PROSPECT

Study objectives

To reduce thromboembolic events from 10% to 3% within three months with treatment with Enoxaparin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval granted from the local ethical committee (Charite - Universitaetsmedizin Berlin Ethik-Kommission) on the 29th March 2004 (ref: 69/2004).

Primary study design
Interventional

Study design
Prospective open multi-centr, randomised controlled phase IIb trial

Study type(s)
Treatment

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

Interventions
After stratification according to Karnofsky Performance Status (KPS), kidney function, tumour stage, recurrent disease, primary disease, DVT in the past patients will be randomised to treatment with/without enoxaparin.

Patients with KPS greater than 80% and normal kidney function receive gemcitabine 1 g/m² (30 minutes), cisplatin 30 mg/m² (90 minutes), 5-fluorouracil 750 mg/m² (24-hours) and folinic acid 200 mg/m² (30 minutes) (GFFC), with/without low molecular weight heparin (LMWH) on days 1 and 8 every three weeks with/without enoxaparin 1 mg/kg daily subcutaneously (sc).

Patients with KPS less than 80% and increased creatinine plasma levels (greater than 1.3 mg/dl) receive the current standard therapy (gemcitabine 1 g/m² (30 minutes) on days 1, 8 and 15 every four weeks) with/without enoxaparin 1 mg/kg daily sc.

After 12 weeks of initial chemotherapy all patients who have not progressed received the standard therapy (gemcitabine 1 g/m² (30 minutes) on days 1, 8 and 15 every four weeks) with /without enoxaparin 40 mg daily sc.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)

Enoxaparin

Primary outcome(s)

To reduce thromboembolic events from 10% to 3% within three months (Kaplan Meyer estimation).

Key secondary outcome(s)

1. Reduction of thromboembolic rate at timepoints 6, 9 and 12 months (Kaplan Meyer estimation)
2. Time to progression
3. Overall survival, progression free survival: Kaplan Meyer Plot (current version of SPSS)
4. Rate of remission: description with tabulations, as percentage of the two treatment groups, duration of remission
5. Toxicity: National Cancer Institute (NCI) Common Toxicity Criteria (CTC) grade differentiation, description with tabulations
6. Quality of life: tabulation descriptions, assesment with box-plot (current version of SPSS)

Completion date

01/04/2009

Eligibility

Key inclusion criteria

1. Histologically or cytologically proven advanced pancreatic cancer stage Iva, b
2. No previous tumour specific therapy of the main tumor or distant metastases
3. Karnofsky Performance Status (KPS) greater than 50%
4. Measurable disease visible per computed tomography (CT) or magnetic resonance tomography (MRT) not older than 14 days
5. No previous deep vein thrombosis (DVT) of the legs within last two years
6. Leucocytes greater than $3.5 \times 10^9/L$, platelets greater than $100 \times 10^9/L$
7. Written informed consent
8. Age of 18 years or more
9. Sufficient contraception up to six 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

Key exclusion criteria

1. Indication for anticoagulation therapy
2. Previous bleeding within two weeks before or increased danger of bleeding
3. Body weight less than 45 kg or greater than 100 kg
4. Pregnant or breastfeeding women
5. Heavy disorders, contradictory with study (as decided by physician)
6. Hyperesthesia against study medication or related drugs
7. Patients with renal failure (creatinine clearance less than 30 ml/min)

Date of first enrolment

01/04/2004

Date of final enrolment

01/04/2009

Locations**Countries of recruitment**

Germany

Study participating centre

Augustenburger Platz 1

Berlin

Germany

13353

Sponsor information**Organisation**

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

ROR

<https://ror.org/001w7jn25>

Funder(s)**Funder type**

Industry

Funder Name

Sanofi-Aventis Deutschland GmbH (Germany)

Funder Name

Lilly Deutschland GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	protocol	20/06/2015	27/10/2022	Yes	No
Protocol article		05/12/2008		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes