ISRCTN02140505 https://doi.org/10.1186/ISRCTN02140505

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 [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/12/2007	**Overall study status** Completed	
Last Edited 27/10/2022	**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

Contact name
Dr Helmut Oettle

Contact details
Augustenburger Platz 1
Berlin
Germany
13353
+49 (0)30 450 553 222
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.: 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).

Study design
Prospective open multi-centr, randomised controlled phase IIb 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 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/m^2 (30 minutes), cisplatin 30 mg/m^2 (90 minutes), 5-fluorouracil 750 mg/m^2 (24-hours) and folinic

acid 200 mg/m^2 (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/m^2 (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/m^2 (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 measure
To reduce thromboembolic events from 10% to 3% within three months (Kaplan Meyer estimation).

Secondary outcome measures
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 differentation, description with tabulations
6. Quality of life: tabulation descriptions, assesment with box-plot (current version of SPSS)

Overall study start date
01/04/2004

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 x 10^9/L, platelets greater than 100 x 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
540

Total final enrolment
312

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)

Sponsor details
Augustenburger Platz 1
Berlin
Germany
13353
+49 (0)30 450 553 222
lars.roll@charite.de

Sponsor type
University/education

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

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	05/12/2008		Yes	No
Results article		20/06/2015	27/10/2022	Yes	No