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A phase II randomised study of chemo-anticoagulation (Gemcitabine-Dalteparin) vs Chemotherapy alone (Gemcitabine) for locally advanced and metastatic pancreatic adenocarcinoma

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2012	Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-of-chemotherapy-with-or-without-dalteparin-for-advanced-pancreatic-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00462852

Secondary identifying numbers
N0084122253

Study information

Scientific Title

Study objectives
To assess the reduction in incidence of venous thrombo-embolism by immediate therapeutic anti-coagulation.

As of 06/08/09 this record has been extensively updated. All updates can be found under the relavent field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised controlled 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
Current information as of 06/08/09:
Patients are stratified according to disease progression (locally advanced vs metastatic) and Karnofsky performance status (≥ 80% vs < 80%), then randomised to 1 of 2 treatment arms:
Arm I: Patients receive gemcitabine hydrochloride IV over 30 minutes once weekly in weeks 1-7 and 9-11.

Arm II: Patients receive low molecular weight dalteparin subcutaneously once daily in weeks 1-12. Patients also receive gemcitabine hydrochloride as in arm I. Blood samples are acquired at baseline for analysis of circulating tissue factor and vascular endothelial growth factor. After completion of study treatment, patients are followed periodically.

Initial information at time of registration:
Randomised controlled trial comparing (a) gemcitabine anticoagulation therapy versus (b) gemcitabine standard treatment.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Gemcitabine-Dalteparin

Primary outcome measure
Added 06/08/09:
Incidence of venous thromboembolism reduction

Secondary outcome measures
Added 06/08/09:
1. Early survival benefits
2. Toxicity
3. Overall survival
4. Time to disease progression
5. Effect of drug combination on serological markers of thromboangiogenesis

Overall study start date
06/01/2003

Completion date
01/12/2006

Eligibility

Key inclusion criteria
Added 06/08/09:
1. Histologically or cytologically confirmed metastatic or locally advanced adenocarcinoma of the pancreas (Patients with clinical 'high probability' of pancreatic cancer and biopsy suggestive but not diagnostic of pancreatic cancer may be eligible based on review by the principal investigator)
2. Measurable or evaluable disease
3. Karnofsky performance status (PS) 60-100% OR WHO PS 0-2
4. Life expectancy > 12 weeks
5. Absolute neutrophil count > 2,000/mm^3
6. WBC > 3,000/mm^3
7. Platelet count > 100,000/mm^3

8. Creatinine clearance > 50 mL/min
9. INR ≤ 1.5 times upper limit of normal (ULN)
10. Bilirubin < 1.5 times ULN (stent allowed)
11. Adequate contraceptive measures in place

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
98

Key exclusion criteria
Added 06/08/09:
1. Clinical evidence of active venous thromboembolism
2. Pregnant or lactating
3. Cerebrovascular incident within the last 6 months
4. Obvious contraindication to anticoagulation, including the following:
4.1. Bleeding diathesis
4.2. Active peptic ulcer
4.3. Ulcerating cancer into duodenum
5. History of other advanced malignancy
6. Gross hematuria
7. Melaena or gross evidence of gastrointestinal bleeding (other than piles)
8. Requiring a central line
9. Prior concurrent therapy
10. Other significant medial or psychiatric illness that, in the opinion of the investigator, would preclude study participation

Date of first enrolment
06/01/2003

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Oncology
Hull
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Industry

Funder Name
The North and South Bank Research and Development Consortium (UK) (NHS R&D Support Funding)

Funder Name
Pfizer Inc

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	01/07/2010		Yes	No
Results article	results	01/06/2012		Yes	No