ISRCTN76464767 https://doi.org/10.1186/ISRCTN76464767

# 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

**ClinicalTrials.gov (NCT)**
NCT00462852

### Protocol serial number
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

### Primary study design
Interventional

### Study design
Multicentre randomised controlled trial

### Study type(s)
Treatment

### 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(s)
Added 06/08/09:
Incidence of venous thromboembolism reduction

### Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex

All

### 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
United Kingdom

England

### Study participating centre
**Department of Oncology**
Hull
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## Sponsor information

### Organisation
Department of Health (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

## 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 |