

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

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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 relevant 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 ($\geq 80\%$ 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/mm³
6. WBC > 3,000/mm³
7. Platelet count > 100,000/mm³

- 8. Creatinine clearance > 50 mL/min
- 9. INR \leq 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
United Kingdom
HU8 9HE

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

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