Does intraperitoneal streptokinase enhance the drainage of loculated ascites in patients with ovarian carcinoma?

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	Results
Last Edited	Condition category	Individual participant data
20/04/2016	Cancer	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

 ${\bf Clinical Trials. gov\ number}$

Secondary identifying numbers

N0063083910

Study information

Scientific Title

Does intraperitoneal streptokinase enhance the drainage of loculated ascites in patients with ovarian carcinoma?

Study objectives

To establish the role of fibrinolytic therapy in the management of loculated ascites in metastatic ovarian carcinoma.

Fibrinolysis has been shown to enhance drainage from the pleural space in empysema and loculated pleural effusion (including malignant pleural effusion). Daily instillation of agents such as Streptokinase via a pleural drain is thought to lyse fibrinous septa and hence open loculi to drainage. This occurs without significant local haemorrhagic complications or activation of systemic fibrinolysis.

Occasionally malignant ascites becomes loculated, possibly due to inflammation or haemorrhage from previous drainage procedures, and this greatly hinders future drainage leaving the patient with the discomfort caused by large volume ascites. If fibrinolytics have the same effect in the peritoneal space as in the pleural space this problem could be overcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

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

Cancer: Ovarian

Interventions

Arm A: Streptokinase

Arm B: Placebo via the peritoneal drain

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Net volume of ascitic fluid drained post Streptokinase/saline

Secondary outcome measures

- 1. Change in abdominal girth
- 2. Ultrasound estimation of residual fluid (largest fluid pocket)
- 3. Patient symptomatology (subjective change in discomfort)
- 4. Time interval to reaccumulation of ascites requiring drainage

Overall study start date

21/07/2000

Completion date

25/02/2004

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Female

Target number of participants

20 NHS patients per year from the Trust split 50%:50% on to standard arm and experimental treatment arm.

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

21/07/2000

Date of final enrolment

Locations

Countries of recruitment

England

United Kingdom

Study participating centre X-Ray Diagnostic

Manchester United Kingdom M20 4BX

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

Government

Funder Name

Christie Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration