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

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 20/04/2016	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Net volume of ascitic fluid drained post Streptokinase/saline

Key secondary outcome(s)

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

Completion date
25/02/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
21/07/2000

Date of final enrolment
25/02/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
X-Ray Diagnostic
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Christie Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration