

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

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Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/04/2016	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

Study design

Randomised controlled trial

Primary study design

Interventional

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