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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.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

25/02/2004

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 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