

A randomised study to evaluate the impact of malignant ascites on well-being and the role of breathing exercises in delaying the reaccumulation of recurrent ascites

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/10/2019	Condition category Cancer	<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

Contact name

Dr - -

Contact details

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Additional identifiers

Protocol serial number

OV4

Study information

Scientific Title

A randomised study to evaluate the impact of malignant ascites on well-being and the role of breathing exercises in delaying the reaccumulation of recurrent ascites

Study objectives

Not provided at time of registration

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)

Not Specified

Health condition(s) or problem(s) studied

Ovary cancer

Interventions

Following the first ascitic tap patients are randomised to either:

1. Group A: No initial intervention, on recurrence requiring a second ascitic tap patients are taught breathing exercises and required to wear a form of abdominal binder. Treatment to continue until reaccumulation of ascites.
2. Group B: Patients are taught breathing exercises and required to wear a form of abdominal binder. On recurrence requiring a second ascitic tap patients are given daily diuretic therapy with frusemide and spironolactone until reaccumulation of ascites.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/05/1997

Eligibility

Key inclusion criteria

1. Recurrent abdominal ascites that are a result of relapsed primary resistant cancer of the ovary
2. The ascites is asymptomatic and requires drainage
3. Patients must not be in sub-acute or complete bowel obstruction
4. Performance status <3
5. Life expectancy of at least 12 weeks
6. No longer receiving chemotherapy
7. Adequate haematological profile and biochemistry

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

01/01/1992

Date of final enrolment

01/05/1997

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Smith and Nephew Foundation (UK)

ROR

<https://ror.org/03agge938>

Funder(s)**Funder type**

Research organisation

Funder Name

North West Thames Research and Development (UK)

Funder Name

Smith and Nephew Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration