

# 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

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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes