

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

UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1992

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

Age group

Not Specified

Sex

Female

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Smith and Nephew Foundation (UK)

Sponsor details

15 Adam Street

London

United Kingdom

WC2N 6LA

Sponsor type

Industry

Website

<http://www.snfoundation.org.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

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