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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	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 31/10/2019	**Condition category** Cancer	[_] Individual participant data [_] 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