ISRCTN13223892 https://doi.org/10.1186/ISRCTN13223892

A randomised trial comparing the efficacy of intraperitoneal (IP) drainage with or without intraperitoneal cisplatin for malignant ascites in gastrointestinal cancer

Submission date
19/08/2002

Recruitment status
No longer recruiting

Registration date
19/08/2002

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
Prof David Cunningham

Contact details
Department of Medicine
Royal Marsden NHS Trust
Downs Road
Sutton
Surrey
United Kingdom
SM2 5PT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RMH E/C 1009

Study information

Scientific Title
A randomised trial comparing the efficacy of intraperitoneal (IP) drainage with or without intraperitoneal cisplatin for malignant ascites in gastrointestinal cancer

Acronym
IPCISPLATIN

Study objectives
To determine the ascites-free survival of intraperitoneal (IP) drainage with IP cisplatin for malignant ascites in gastrointestinal (GI) cancer.

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

Health condition(s) or problem(s) studied
Oesophagus/stomach cancer

Interventions
Two arms:
1. IP drainage alone
2. IP drainage and IP cisplatin

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cisplatin

Primary outcome measure
1. Toxicity
2. Ascites free survival
3. Time to ascites re-accumulation
4. Overall survival

Secondary outcome measures
No secondary outcome measures

Overall study start date
05/07/1994

Completion date
31/08/2002

Eligibility

Key inclusion criteria
1. Histologically verified locally advanced or metastatic adenocarcinoma of the gastrointestinal tract
2. Clinically confirmed symptomatic ascites
3. Glomerular filtrate rate of >40ml/min
4. Patients must not have received intraperitoneal cisplatin before
5. No concurrent intravenous cisplatin, and at least a 2 week gap after the completion of intravenous cisplatin before intraperitoneal therapy can be commenced
6. Intravenous chemotherapy (except cisplatin) may be given concurrently
7. No medical contraindications to treatment

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
17

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
05/07/1994

Date of final enrolment
01/11/1996

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Medicine
Surrey
United Kingdom
SM2 5PT

Sponsor information

Organisation
The Royal Marsden NHS Foundation Trust (UK)

Sponsor details
Downs Road
Sutton
England
United Kingdom
SM2 5PT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Marsden Hospital (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