

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	<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 14/02/2018	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

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Department of Medicine

Surrey

United Kingdom

SM2 5PT

Sponsor information

Organisation

The Royal Marsden NHS Foundation Trust (UK)

ROR

<https://ror.org/0008wzh48>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Marsden Hospital (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration