

A randomised double-blind controlled trial of BCNU as second-line therapy in metastatic oesophago-gastric, colorectal and pancreatic 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 15/12/2015	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

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London
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NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A randomised double-blind controlled trial of BCNU as second-line therapy in metastatic oesophago-gastric, colorectal and pancreatic cancer

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)

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

Colon, oesophagus, pancreas, rectum, stomach cancers

Interventions

1. Arm 1: BCNU 200 mg in 500 ml 5% dextrose
2. Arm 2: 5% dextrose alone

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

BCNU

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1995

Completion date

31/03/2001

Eligibility

Key inclusion criteria

Any patient who has progressed on or has a short disease free interval with folinic acid modulated 5-Fluorouracil (5FU) protracted infusional 5FU regimens

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1995

Date of final enrolment

31/03/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

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