

A randomised trial comparing 8 cycles of CPT11 with CPT11 until disease progression in patients with colorectal cancer resistant to 5-fluorouracil

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 15/12/2015	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
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Additional identifiers

Protocol serial number
RMH E/C 1475

Study information

Scientific Title
A randomised trial comparing 8 cycles of CPT11 with CPT11 until disease progression in patients with colorectal cancer resistant to 5-fluorouracil

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

1. CPT11 350 mg/m² IV over 30 min every 3 weeks
2. No treatment

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Histological evidence of metastatic adenocarcinoma of colon or rectum not amenable to surgery or radiotherapy
2. Documented evidence of disease progression by Computed Tomography (CT) within 24 weeks of last 5FU

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

16/10/1997

Date of final enrolment

31/12/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

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