

A Randomised Trial of 5-Fluorouracil (5FU) and Leucovorin (LV) versus 5-Fluorouracil, leucovorin and Interferon-Alpha 2a for Advanced Colorectal Adenocarcinoma

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/11/2019	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
CR04

Study information

Scientific Title

A Randomised Trial of 5-Fluorouracil (5FU) and Leucovorin (LV) versus 5-Fluorouracil, leucovorin and Interferon-Alpha 2a for Advanced Colorectal Adenocarcinoma

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

Advanced colorectal adenocarcinoma

Interventions

Patients are randomised to one of two treatment arms:

1. Arm 5FU-LV: Chemotherapy with 5-fluorouracil and leucovorin repeated every 14 days for six cycle. Following reassessment patients receive a further six cycles of chemotherapy unless there is evidence of progressive disease.
2. Arm 5FU-LV-IFN: Chemotherapy with 5-fluorouracil and leucovorin plus interferon-alpha repeated every 14 days for six cycle. Following reassessment patients receive a further six cycles of chemotherapy unless there is evidence of progressive disease.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

5-Fluorouracil, Leucovorin, Interferon-Alpha 2a

Primary outcome(s)

Not provided at time of registration.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

01/08/2005

Eligibility

Key inclusion criteria

1. Histologically confirmed adenocarcinoma of the colon or rectum not amenable to surgery or radiotherapy
2. Objectively assessable disease
3. No previous treatment with 5-fluorouracil or interferon
4. Adequate bone marrow function
5. No concurrent uncontrolled medical illness
6. Not on systemic corticosteroids at the time of study entry
7. Life expectancy of >3 months
8. World Health Organisation (WHO) performance status 0-2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

260

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/08/2000

Date of final enrolment

01/08/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Charity

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

[Results article](#)

01/08/1996

15/11/2019

Yes

No