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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 15/11/2019	**Condition category** Cancer	

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 5LU-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, 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 article	results	01/08/1996	15/11/2019	Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes