

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
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/11/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

Not provided at time of registration.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/08/2000

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration.

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

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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London

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+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/1996	15/11/2019	Yes	No