ISRCTN95638591 https://doi.org/10.1186/ISRCTN95638591

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 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 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
20 Park Crescent
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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