ISRCTN32414363 https://doi.org/10.1186/ISRCTN32414363

Adjuvant X-ray & 5-Fluorouracil (5-FU) Infusion Study

Submission date 28/02/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 12/04/2012	**Condition category** Cancer	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=95

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
UK01 (AXIS)

Study information

Scientific Title

Acronym
AXIS

Study objectives
To assess the efficacy and safety of peri-operative radiotherapy for rectal cancer and portal vein infusion of 5-fluorouracil in colon and rectal cancer

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
Cancer

Interventions
There are four treatment groups with all groups receiving surgery.
1. The first group receives peri-operative radiotherapy
2. The second group receives portal-vein infusion
3. The third group receives peri-operative radiotherapy plus portal-vein infusion
4. The fourth group receives surgery alone

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fluorouracil (5-FU)

Primary outcome(s)
Survival time; Local recurrence; Metastases

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/1997

Eligibility

Key inclusion criteria

1. Suspected malignant carcinoma of rectum or colon
2. The patient must be fit for external radiation therapy (XRT) or 5-FU if allocated
3. The surgeon is uncertain whether adjuvant treatment is indicated

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
01/11/1989

Date of final enrolment
31/12/1997

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
Research council

Funder Name
Medical Research Council (MRC) (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	01/10/2003		Yes	No