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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Survival time; Local recurrence; Metastases

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/1989

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
4000

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
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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Sponsor type
Research council

Website
http://www.mrc.ac.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

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	01/10/2003		Yes	No