

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

<b>Submission date</b> 28/02/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/02/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/04/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=95](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=95)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Dionne Cain

### Contact details

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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, Medical Research Committee and Advisory 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?
<a href="#">Results article</a>	results	01/10/2003		Yes	No