# A randomised trial of infusional 5-fluorouracil and concomitant radiotherapy in locally advanced rectal cancer, comparing three and six months of infusional 5-fluorouracil

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
19/08/2002	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Completed	Results
Last Edited	Condition category	[] Individual participant data
21/01/2019	Cancer	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

#### Additional identifiers

**Protocol serial number** COLORAD

## Study information

Scientific Title

A randomised trial of infusional 5-fluorouracil and concomitant radiotherapy in locally advanced rectal cancer, comparing three and six months of infusional 5-fluorouracil

#### **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

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Cancer of rectum

#### **Interventions**

All patients receive continuous infusional 5-fluorouracil for 12 weeks plus radiotherapy to the pelvis, minimum 45 Gy given in twenty-five fractions over 5 weeks to start at the beginning of the 5th week of chemotherapy.

Depending upon the initial randomisation, patients receive either:

- 1. Group One: Continuous infusional 5-fluorouracil for a further 12 weeks.
- 2. Group Two: No further chemotherapy with 5-fluorouracil.

#### Intervention Type

Drug

#### Phase

Not Applicable

#### Drug/device/biological/vaccine name(s)

5-fluorouracil

#### Primary outcome(s)

Not provided at time of registration

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

11/11/1994

### Eligibility

#### Key inclusion criteria

- 1. Histologically verified adenocarcinoma of the rectum, which is either:
- 1.1. Inoperable primary tumour
- 1.2. Locally recurrent tumour
- 1.3. Residual pelvic disease after resection as assessed either surgically or histopathologically
- 2. No evidence of metastatic disease
- 3. No past history of malignancy
- 4. No previous radiotherapy to the pelvis
- 5. Normal bone marrow, liver and renal function
- 6. No concurrent severe or life threatening illness

#### 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

01/01/1990

#### Date of final enrolment

11/11/1994

#### Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre MRC Clinical Trials Unit

London United Kingdom NW1 2DA

# Sponsor information

#### Organisation

The Royal Marsden NHS Foundation Trust (UK)

#### **ROR**

https://ror.org/0008wzh48

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Royal Marsden Hospital (UK)

#### **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?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes