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

Recruitment status	<ul><li>Prospectively registered</li></ul>
No longer recruiting	Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	[] Individual participant data
Cancer	<ul><li>Record updated in last year</li></ul>
	Overall study status Completed Condition category

# 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

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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

#### 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

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 measure

Not provided at time of registration

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/01/1990

#### 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** 

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Target number of participants

Not provided at time of registration

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/01/1990

#### Date of final enrolment

# Locations

#### Countries of recruitment

England

**United Kingdom** 

Study participating centre MRC Clinical Trials Unit London United Kingdom NW1 2DA

# Sponsor information

## Organisation

The Royal Marsden NHS Foundation Trust (UK)

## Sponsor details

Downs Road Sutton England United Kingdom SM2 5PT

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/0008wzh48

# Funder(s)

#### Funder type

Hospital/treatment centre

#### Funder Name

Royal Marsden Hospital (UK)

# **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