

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 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/01/2019	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 hypothesis

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

Condition

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

Overall study end date

11/11/1994

Eligibility**Participant 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

Participant exclusion criteria

Not provided at time of registration

Recruitment start date

01/01/1990

Recruitment end date

11/11/1994

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