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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	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 21/01/2019	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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

Primary study design
Interventional

Study design
Randomised controlled trial

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