

Post-Operative Radiotherapy for Selected High Risk Rectal Adenocarcinoma

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 06/11/2012	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
GI/HRR

Study information

Scientific Title

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)

Not Specified

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

Following surgery patients are randomised to one of two treatment arms:

1. Arm A: Post-operative radiotherapy, a midplane dose of 45 Gy given over 4 to 5 weeks
2. Arm B: No radiotherapy

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Histologically proven adenocarcinoma of the rectum
2. Surgery at or below pelvic brim
3. Curative operation, all macroscopic disease removed
4. Aged <80 years, 75 years if physically unfit
5. No previous history of multiple abdominal or pelvic surgical procedures
6. No evidence of small bowel descending into area of maximum dose of radiotherapy
7. Adequate bone marrow function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2000

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Northern and Yorkshire Clinical Trials and Research Unit (UK)

Funder(s)

Funder type

Research organisation

Funder Name

Northern and Yorkshire Clinical Trials and Research Unit (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration