ISRCTN91411631 https://doi.org/10.1186/ISRCTN91411631

Post-Operative Radiotherapy for Selected High Risk Rectal Adenocarcinoma

Submission date	Recruitment status	[ ] Prospectively registered
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
06/11/2012	Cancer	[ ] Record updated in last year

Plain English summary of protocol
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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date

01/01/2000

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

Age group
Adult

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
01/01/2000

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Northern and Yorkshire Clinical Trials and Research Unit (UK)

Sponsor details
-
Leeds
United Kingdom
-

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Northern and Yorkshire Clinical Trials and Research Unit (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