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Pathology-guided treatment of rectal cancer

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 17/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr David Sebag-Montefiore

Contact details
Leeds Cancer Centre
Cookridge Hospital
Hospital Lane
Leeds
United Kingdom
LS16 6QB

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00003422

Protocol serial number
CR07

Study information

Scientific Title
Pathology-guided treatment of rectal cancer: a randomised controlled trial

Study objectives

In inoperable rectal cancer: are local recurrence-free survival rates and quality of life optimised by giving all patients short course pre-operative radiotherapy, or is it a preferable option to give post-operative chemoradiotherapy only to those at high risk of recurrence (i.e. with involved margins following surgery)?

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)
Treatment

Health condition(s) or problem(s) studied
Rectal cancer

Interventions
1. One group receives a short course pre-operative radiotherapy followed by surgery
2. The other group receives surgery followed by postoperative chemo-radiotherapy

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Local recurrence (as defined using an algorithm designed for the trial).

Key secondary outcome(s))
1. Local recurrence-free survival
2. Overall survival
3. Time to appearance of distant metastases
4. Disease-free survival
5. Morbidity
6. Quality of life
7. Economic implications

Completion date
05/08/2005

Eligibility

Key inclusion criteria
1. Histologically confirmed adenocarcinoma of the rectum
2. Considered potentially operable
3. No evidence of metastases
4. Patient considered fit to receive either arm of the trial
5. No concurrent uncontrolled medical illness
6. No previous or current malignant disease likely to interfere with treatment or comparisons
7. Informed consent obtained

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/02/1998

Date of final enrolment
05/08/2005

Locations

Countries of recruitment
United Kingdom

England

Canada

Study participating centre
Leeds Cancer Centre
Leeds
United Kingdom
LS16 6QB

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Initial results:	07/03/2009		Yes	No
Results article	Prospective study results:	07/03/2009		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes