

Pathology-guided treatment of rectal cancer

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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