

# Pathology-guided treatment of rectal cancer

<b>Submission date</b> 06/04/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.ctu.mrc.ac.uk/studies/CR07.asp>

## Contact information

### Type(s)

Scientific

### Contact name

Dr David Sebag-Montefiore

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00003422

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure

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

## Secondary outcome measures

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

## Overall study start date

01/02/1998

## 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

## Age group

Adult

## Sex

Both

## Target number of participants

1350

## 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

Canada

England

United Kingdom

**Study participating centre**

**Leeds Cancer Centre**

Leeds

United Kingdom

LS16 6QB

## **Sponsor information**

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

20 Park Crescent

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+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

**Sponsor type**

Research council

**Website**

<http://www.mrc.ac.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, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Results article</a>	Initial results:	07/03/2009		Yes	No
<a href="#">Results article</a>	Prospective study results:	07/03/2009		Yes	No