

# A randomised trial comparing preoperative short-course radiotherapy with preoperative conventionally fractionated chemoradiation for rectal cancer

<b>Submission date</b> 14/01/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/11/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> 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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## Additional identifiers

### Protocol serial number

4 P05C 03917

## Study information

**Scientific Title**

A randomised study in rectal cancer comparing sphincter preservation following preoperative short-course radiotherapy with immediate surgery or following preoperative conventionally fractionated chemoradiation and delayed surgery

**Study objectives**

Tumour shrinkage after conventional chemoradiation and delayed surgery increases anterior resection rate as compared to preoperative short-course radiotherapy with immediate surgery.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the Regional Ethics Committee at the Maria Skłodowska-Curie Memorial Cancer Centre in Warsaw (Poland) on the 18th January 1999 (ref: 3/99). All other centres have received full ethics approval before the first participant was recruited in that centre.

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Rectal cancer

**Interventions**

Patients are randomised to receive either:

1. Preoperative 5 x 5 Gy irradiation with total mesorectal excision (TME) performed within 7 days, or
2. Chemoradiation (50.4 Gy) followed by TME 4 - 6 weeks later

Living patients were followed up for a median of 48 months, range 31 - 69 months.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Anterior resection rate.

**Key secondary outcome(s))**

1. Long-term overall survival
2. Disease-free survival

3. Local control
4. Quality of life
5. Anorectal function
6. Distal bowel intramural spread
7. Local control in relation to distal bowel margin

**Completion date**

28/02/2002

## Eligibility

**Key inclusion criteria**

1. Clinical stage T3 or cT4 resectable primary tumour
2. No evidence of sphincter involvement on digital rectal examination
3. Lower tumour margin accessible to digital rectal examination
4. No distant metastases
5. Aged 75 years or less, either sex
6. Written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

316

**Key exclusion criteria**

1. T4 fixed tumour
2. Previous irradiation
3. Second primary tumour

**Date of first enrolment**

01/04/1999

**Date of final enrolment**

28/02/2002

## Locations

**Countries of recruitment**

Poland

**Study participating centre**  
**Department of Radiotherapy**  
Warsaw  
Poland  
02-781

## Sponsor information

**Organisation**  
Polish State Committee for Scientific Research (Poland)

**ROR**  
<https://ror.org/05pwfyy15>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Polish State Committee for Scientific Research (Poland)

## Results and Publications

**Individual participant data (IPD) sharing plan**  
Not provided at time of registration

**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="#">Results article</a>		01/07/2004		Yes	No
<a href="#">Other publications</a>		01/07/2005		Yes	No
<a href="#">Other publications</a>		01/09/2005		Yes	No
<a href="#">Other publications</a>		01/05/2006		Yes	No
<a href="#">Other publications</a>		01/10/2006		Yes	No
<a href="#">Other publications</a>		01/02/2007		Yes	No
<a href="#">Other publications</a>		01/09/2007		Yes	No