

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

Anterior resection rate.

Secondary outcome measures

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

Overall study start date

01/04/1999

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

Age group

Adult

Sex

Both

Target number of participants

316

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)

Sponsor details

Wspolna 1/3

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sekretariat.bg@nauka.gov.pl

Sponsor type

Government

Website

<http://kbn.icm.edu.pl>

ROR

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

Funder(s)

Funder type

Government

Funder Name

Polish State Committee for Scientific Research (Poland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article		01/07/2004		Yes	No
Other publications		01/07/2005		Yes	No
Other publications		01/09/2005		Yes	No
Other publications		01/05/2006		Yes	No
Other publications		01/10/2006		Yes	No
Other publications		01/02/2007		Yes	No
Other publications		01/09/2007		Yes	No