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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

Registration date
30/01/2008

Overall study status
Completed

Last Edited
14/11/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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 Sklodowska-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.

Primary study design
Interventional

Study design
Randomised controlled trial

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?
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