

The Finnish Rectal Cancer Study

Submission date 23/02/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/07/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/04/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Rectal cancer (cancer of the rectum) affects the lower part of the large bowel that connects to the anus. Total mesorectal excision (TME) is a common procedure used in the treatment of rectal cancer in which a significant length of the bowel around the cancer is removed. The introduction of TME surgery has reduced local relapses (where the cancer comes back) but recurrence still remains a clinical problem. Preoperative radiotherapy (before surgery) to shrink the cancer has an effect but a survival benefit has been seen in only one study. These studies were conducted in the era of conventional surgery. The aim of this study is to find out whether preoperative short-term radiotherapy can reduce local recurrence with TME surgery and whether postoperative adjuvant chemotherapy (after surgery) would lead to improved survival rates.

Who can participate?

Patients aged 18-80 with rectal cancer

What does the study involve?

Participants randomly allocated to be treated with either TME surgery only or radiotherapy followed by TME surgery in 1 week or less. Radiotherapy is given on 5 consecutive days. Postoperative chemotherapy consists of six cycles and begins 4-6 weeks after surgery. All participants are followed up for at least five years after surgery to assess survival and recurrence rates.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Helsinki University Hospital (Finland)

When is the study starting and how long is it expected to run for?

January 1995 to June 2011

Who is funding the study?

Helsinki University Hospital (Finland)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A prospective randomized multicenter trial to compare the results of combined short-term preoperative radiotherapy, postoperative 5-FU based chemotherapy and total mesorectal excision with total mesorectal excision alone in the treatment of resectable rectal cancer

Study objectives
Total mesorectal excision (TME) and short term preoperative radiotherapy together with postoperative chemotherapy leads to better 5 year survival and lower local recurrence rate than TME alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of Helsinki University Hospital, 20/12/1994

Study design

Randomized prospective multicenter trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Rectal cancer

Interventions

After informed consent had been received patients were randomized at the Finnish Cancer Registry. The randomization process was a true one, no blocks were used. The randomization was done between surgery only and 5x5Gy radiotherapy followed by surgery in one week or less. Radiotherapy was given from 3-4 fields on 5 consecutive days.

Postoperative chemotherapy consisted of bolus 5-fluorouracil (5-FU) treatment in the beginning of the study and intravenous infusion towards the end of the study. Chemotherapy consisted of six cycles and was begun 4-6 weeks after surgery. All patients were followed up at least five years after surgery.

Radiotherapy: 25 Gy (5x5Gy), 4 fields, 5 cm craniocaudal margins, 3 cm anteroposterior and lateral margins. Time interval between radiotherapy and surgery not more than 7 days.

Surgery: Total mesorectal excision with mobilisation of splenic flexure. Choice between anterior resection or abdominoperineal excision in low tumours made at the operation. Diversion recommended.

Chemotherapy: 3-10 weeks after surgery at 350mg/m² 5-FU intravenous bolus on 5 consecutive days + 20mg/m² leucovorin immediately before 5-FU. Six cycles, interval 3-4 weeks.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

5-fluorouracil, leucovorin

Primary outcome measure

1. 5 year survival
2. 5 year local recurrence rate

Secondary outcome measures

Postoperative complications

Overall study start date

01/01/1995

Completion date

30/06/2011

Eligibility**Key inclusion criteria**

1. Aged 18 - 80 years
2. Clinical stage II-III primary rectal adenocarcinoma

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

280

Key exclusion criteria

1. Obstructive tumours
2. Tumours invading adjacent organs
3. Patients with a diagnosis of another cancer less than five years previously, with ulcerative colitis
4. Crohn's disease
5. Familial polyposis
6. Hereditary nonpolypotic colorectal carcinoma

Date of first enrolment

01/01/1995

Date of final enrolment

30/06/2011

Locations

Countries of recruitment

Finland

Study participating centre

Alkutie 81a

Helsinki

Finland

00660

Sponsor information

Organisation

Helsinki University Hospital (Finland)

Sponsor details

PL340

Helsinki

Finland

00290

Sponsor type

Hospital/treatment centre

Website

<http://www.hus.fi/>

ROR

<https://ror.org/02e8hzf44>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Helsinki University Hospital (Finland)

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