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The Finnish Rectal Cancer Study

Submission date 23/02/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/07/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/04/2017	**Condition category** Cancer	[_] Individual participant data [_] 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 immeadiately 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