ISRCTN74475000 https://doi.org/10.1186/ISRCTN74475000

Neoadjuvant short-term radiotherapy followed by surgery versus surgery alone for patients over 70 years of age with local advanced rectal cancer and who are medically unfit for standard neoadjuvant radiochemotherapy treatment

Submission date
06/06/2012

Recruitment status
No longer recruiting

Registration date
16/10/2012

Overall study status
Completed

Last Edited
31/03/2017

Condition category
Cancer

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Rectal cancer is cancer that starts in the rectum, the lower part of the large bowel. Locally advanced rectal cancer means that the cancer has spread into the tissues around the rectum but hasn't spread to other organs. The aim of this study is to find out whether it is better to treat patients aged over 70 with radiotherapy before they undergo surgery to remove the cancer.

Who can participate?
Patients aged over 70 with locally advanced rectal cancer who are medically unfit for standard radiochemotherapy treatment

What does the study involve?
Participants are randomly allocated to one of two groups. One group are treated with radiotherapy followed by surgery followed by chemotherapy if tolerated. The other group are treated with surgery followed by chemotherapy. Both groups are followed up to see which treatment has better results.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
South City Hospital Rostock (Klinikum Suedstadt Rostock) (Germany)

When is the study starting and how long is it expected to run for?
January 2013 to January 2021

Who is funding the study?
South City Hospital Rostock (Klinikum Suedstadt Rostock) (Germany)

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
2007-006758-24

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
NEROP-RC (NEoadjuvant Radiotherapy for Older Patients Rectal Cancer): a randomised controlled phase III study

Acronym
NEROP-RC

Study objectives
The primary aim of the study is to demonstrate the superiority of preoperative radiotherapy (5x5Gy) followed by total mesorectal excision (TME) or abdomino-sacral rectum extirpation in patients over 70 years of age with locally advanced rectal cancer, up to a max. of uT1-3N1-2M0

versus surgery alone with TME or abdomino-sacral rectum extirpation with regard to locoregional control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Rostock Ethics Commission, 31/05/2010, ref: FK-2010-0008

Study design
Prospective randomised controlled multicentre phase III study

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
Optimal therapy for patients > 70 years with rectal cancer

Interventions
All patients over 70 years of age and having preoperatively diagnosed locally advanced rectal cancer (uT1-3 and/or uN1-2), for whom the neoadjuvant standard RCT appears to present too high a risk, are randomised to two study arms:

Arm A: neoadjuvant short-term RT (5x5Gy) followed by TME or abdominosacral rectum extirpation

Arm B (control arm): TME alone or abdomino-sacral rectum extirpation.

Four weeks following surgery re-evaluation takes place in both arms if possible, then administration of 5-FU- based Chemotherapy (CT) for 6 months. If no CT is possible, then control arm is followed up.

Intervention Type
Mixed

Primary outcome measure
Superiority of preoperative radiotherapy (5x5Gy) followed by TME and abdomino-sacral rectum extirpation in patients over 70 years of age with locally advanced rectal cancer up to a maximum

of uT1-4N1-2M0 versus surgery alone with TME or abdomino-sacralen rektum extirpation with respect to locoregional control.

Secondary outcome measures
1. Disease-free survival (DFS) (first case of tumor illness locoregional or distant metastases)
2. Occurrence of distant metastases
3. Frequency of other, non-tumor-related deaths
4. Determination for comorbidity based on the Charlson Index and the ADL Index
5. Determination of how often chemotherapy can be performed postoperatively
7. Acute and long-term toxicity of preoperative radiotherapy
8. Overall survival (OS)

Overall study start date
01/01/2013

Completion date
01/01/2021

Eligibility

Key inclusion criteria
1. Patients with primary diagnosis of histologically bioptically secured diagnosis of rectal cancer
2. Rectal cancer at any height (up to 16cm lower edge of tumor measured from the anal line using inflexible rectoscopy)
3. Decision made by the treating tumor team that intensified RCT is not possible
4. Preoperative tumor staging max. uT1-4uN1-2M0
5. Age >/= 70 years
6. Karnofsky index >/= 70%
7. ASA-classification < IV
8. Oral and written consent according to
9. Good Clinical Practice and corresponding local, national and international regulations

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
The study was originally designed to include 800 patients, 400 patients in each arm

Key exclusion criteria
1. Other previous cancer illnesses with the exception of appropriately treated in situ carcinoma of the cervix or skin tumors with no indication of melanoma or in cases of tumor-free state ≥ 10 years subsequent to appearance of cancer which has undergone appropriate treatment
2. Participation in studies elsewhere which include chemotherapy or radiotherapy
3. Inability to participate in regular check-ups

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2021

Locations

Countries of recruitment
Germany

Study participating centre
Klinikum Suedstadt Rostock
Rostock
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18059

Sponsor information

Organisation
South City Hospital Rostock (Klinikum Suedstadt Rostock) (Germany)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.kliniksued-rostock.de

ROR
https://ror.org/02m0p4y77

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
South City Hospital Rostock (Klinikum Suedstadt Rostock), Department of Surgery (Germany)

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