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Simply Capecitabine in rectal cancer after irradiation plus total mesorectal excision (TME)

Submission date	Recruitment status	[_] Prospectively registered
14/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/02/2016	Cancer	

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
NTR552; CKTO 2003 - 16

Study information

Scientific Title
Added 10/08/09:
A Multicenter Phase III Randomised Trial comparing Total Mesorectal Excision with Pre-

operative Radiotherapy with or without Post-operative Oral Capecitabine in the Treatment of Operable Primary Rectal Cancer.

Acronym
SCRIPT

Study objectives
The overall survival in the arm treated without chemotherapy (TNM-stage II or III tumours) is expected to be approximately 60%. Assuming an improvement in overall survival from 60% to 70% in the arm treated with chemotherapy (TNM-stage II or III tumours), 840 patients are needed; 420 in each arm (alpha 0.05, two sided; power 0.90).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised open label active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rectal cancer, tumour

Interventions
Subjects will be randomised 1:1 to receive either 24 weeks of post-operative treatment (8 courses) with oral capecitabine twice daily, given on days 1-14 every 21 days versus no post-operative treatment (observation).

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
To investigate in rectal cancer patients, in a randomised fashion, whether post-operative chemotherapy leads to a substantial improvement in overall survival, when standardised TME-surgery and pre-operative radiotherapy and pathology are applied.

Key secondary outcome(s))
1. To investigate in a randomised fashion whether post-operative chemotherapy leads to a substantial improvement in local and distant tumour control, when standardised TME-surgery, pre-operative radiotherapy and pathology are applied
2. Standardisation and quality control of TME-surgery and pathology

Completion date
01/09/2007

Eligibility

Key inclusion criteria
1. Rectal adenocarcinoma confirmed by histological examination of the biopsy specimen, located below the level of S1/S2 on a barium enema, computed tomography (CT) scan or magnetic resonance imaging (MRI) scan, or located within 15 cm of the anal verge, measured during withdrawal of the flexible scope
2. Preoperative short term hypofractioned radiotherapy (5 x 5 Gy)
3. TME-surgery performed
4. TNM-stage II (T3-T4, N0) or III (any T, N+) as defined by postoperative examination of the resected specimen
5. Start of chemotherapy treatment is possible within 6 weeks after surgery
6. WHO performance score =/< 2
7. Patient is considered to be mentally and physically fit for chemotherapy as judged by the medical oncologist
8. Age >/= 18 years
9. Written informed consent
10. Adequate potential for follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. Evidence of macroscopic residual disease (R2)
2. T1 or T2 tumour with the presence of micrometastasis without the presence of macrometastasis
3. Contraindications to chemotherapy, including adequate blood counts (measured after recovery from surgery):
3.1. White blood count >/= 4.0 x 10^9/l
3.2. Platelet count >/= 100 x 10^9/l
3.3. Clinically acceptable haemoglobin levels
3.4. Creatinine levels indicating renal clearance of >/= 60 ml/min
3.5. Bilirubin <25 µmol/l
4. Familial Adenomatosis Polyposis coli (FAP), Hereditary Non-Polyposis Colorectal Cancer

(HNPCC), active Crohns disease or active ulcerative colitis
5. Concomitant malignancies, except for adequately treated basocellular carcinoma of the skin or in situ carcinoma of the cervix uteri. Subjects with prior malignancies must be disease-free for at least 10 years.
6. Known DPD deficiency

Date of first enrolment
01/10/2004

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Dutch Colorectal Cancer Group (DCCG), University Medical Centre St Radboud (Netherlands)

ROR
https://ror.org/00nsb1162

Funder(s)

Funder type
Charity

Funder Name
National Cancer Fund (Koningin Wilhelmina Fonds [KWF]) (Netherlands)

Funder Name

Roche Nederland BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

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	results	01/04/2015		Yes	No