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Radiation therapy plus capecitabine and oxaliplatin chemotherapy and bevacizumab anti-angiogenetic therapy in locally advanced rectal cancer

Submission date
14/04/2008

Recruitment status
No longer recruiting

Registration date
09/05/2008

Overall study status
Completed

Last Edited
09/05/2008

Condition category
Cancer

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

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
Final 01/12.11.07

Study information

Scientific Title

Phase II trial: Pre-operative, long-term chemoradiation with capecitabine, oxaliplatin and bevacizumab in locally advanced rectal cancer

Acronym
BevXelOx-RT

Study objectives
Efficacy of neoadjuvant radio-chemotherapy will be improved by an additional angiogenesis-inhibiting therapy using the vascular endothelial growth factor (VEGF) antibody bevacizumab.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty, University of Lübeck. Date of approval: 26/02/2008

Study design
Open-label, single-arm, non-randomised, phase II study.

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Locally advanced rectal cancer

Interventions
All participants will receive the following (single-arm study):
1. Radiotherapy: 5 × weekly 1.8 Gy to a total dose of 50.4 Gy
2. Chemotherapy: Capecitabine 1,650 mg/sqm orally (p.o.), (divided in 2 single doses) daily on days 1-14 and 22-35; oxaliplatin 50 mg/sqm intravenously (i.v.) on days 1, 8, 22, 29 over a 120-min infusion with 500 ml 5% glucose; bevacizumab 5 mg/kg i.v. as short time infusion (30-90 min) prior to oxaliplatin administration on days 1, 15, 29.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Capecitabine, oxaliplatin, bevacizumab.

Primary outcome(s)
Histopathological complete remission rate at time of surgery (approximately 4 weeks following study treatment)

Key secondary outcome(s))

1. Pathological downstaging at time of surgery (approximately 4 weeks following study treatment)
2. Regression grading (according to Dvorak) at time of surgery (approximately 4 weeks following study treatment)
3. Sphincter preservation at time of surgery (approximately 4 weeks following study treatment)
4. Acute and subacute toxicity during study treatment, especially:
4.1. (Post)operative complications
4.2. Gastrointestinal perforation
4.3. Wound healing complications
4.4. Bleeding complications

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Age >18 years, both males and females
2. Patients with histologically proven adenocarcinoma of the rectum, tumour = 16 cm from the anal verge, u T3-4 or uN+ or Mason III/IV, staging will must be done by endorectal ultrasound and magnetic resonance imaging (MRI) or by endorectal unltrasound and high resolution computed tomography, no evidence of metastatic disease
3. No prior treatment, except for ileostomy (if necessary due to ileus)
4. No fistulas near the tumour
5. Eastern Cooperative Oncology Group (ECOG) Performance Status <= 1
6. Adequate bone marrow, hepatic and renal function:
6.1. Haemoglobin >10.0 g/dL, leucocyte count > 3.5 x 109/L, absolute neutrophil count >1.5 x 109 /L, platelet count >100 x 109/L
6.2. Alkaline phosphatase, alanine aminotransferase (ALAT), aspartate aminotransferase (ASAT) <3 x upper limit of normal (ULN)
6.3. Total bilirubin <= 2 mg/dL
6.4. Creatinine clearance >50 mL/min
6.5. Creatinine <= 1.5 x ULN
7. Patients must have understood the contents of the protocol and signed written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. No presence of adequate contraception in fertile patients
2. Pregnant or breastfeeding women
3. Previous or persistent alcohol or drug abuses
4. Prior radiotherapy or chemotherapy to the pelvis, for any reason
5. Treatment with any investigational drug, agent nor procedure, (i.e. did not participate in another trial) within 4 weeks before entry in this trial
6. Treatment with other anti-cancer agents
7. Patients not able or willing to comply with the protocol treatment and investigations
8. Patients with uncontrolled severe somatic or psychological diseases, e.g.:
8.1. Despite medication uncontrolled cardiac diseases, myocardial infarction within the last 6 months prior to enrolment
8.2. Neurological or psychiatric disorders including seizures and dementia
8.3. Active, uncontrolled infection and sepsis
9. Symptomatic peripheral neuropathy >= grade 2 (National Cancer Institute - Common Terminology Criteria for Adverse Events [NCI CTCAE])
10. Concurrent malignancies, with the exception of successfully treated cone-biopsied in situ carcinoma of the cervix or basal cell carcinoma of the skin
11. Chronic diarrhoea > grade 1 (NCI CTCAE)
12. Chronic inflammatory bowel disease or other pre-existing condition which would deter resorption of drugs (e.g. dumping syndrome, evidence of accelerated small bowel passage, evidence of deterred resorption due to gastric or bowel surgery)
13. Known hypersensitivity to platinum-containing drugs
14. Concurrent use of the antiviral agent sorivudine or chemically related analogues
15. Known dihydropyrimidine dehydrogenase deficiency
16. Known allergy to any of the study drugs or its ingredients
17. Interstitial pneumonia or extensive, symptomatic lung fibrosis
18. Organ allograft requiring immunosuppressive therapy
19. Severe, non-healing wounds, ulcers or fractures
20. Thrombosis or severe bleeding (except for bleeding of the tumour) within 6 months prior to enrolment
21. Bleeding diathesis or thrombophilia
22. Therapeutic anticoagulation (with marcumar or heparin)
23. Acetylsalicylic acid >325 mg per day or routine use of non-steroidal anti-inflammatory drugs which inhibit the function of platelets
24. Ascites nescessitating puncture
25. Patients with proteinuria >= 1+ at baseline, as long as a 24hour urine collection demonstrates >500 mg of protein/ 24 hr
26. Concurrent treatment with St. John's wort
27. Major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to study treatment start, or anticipation of the need for major surgical procedure during the preoperative chemoradiation (exceptions: protective ileostomy and the planned resection of the rectal cancer)

Date of first enrolment
01/05/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsklinikum Schleswig-Holstein
Lübeck
Germany
23538

Sponsor information

Organisation
University Medical Centre Schleswig-Holstein (Universitätsklinikum Schleswig-Holstein) (Germany)

ROR
https://ror.org/01tvm6f46

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Schleswig-Holstein (Universitätsklinikum Schleswig-Holstein) (Germany)

Funder Name
Roche Pharma AG (Germany)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes