KURZPROTOKOLL
PETACC-6

Öffentlicher Titel	Capecitabin mit oder ohne Oxaliplatin nach neoadjuvanter Therapie von lokal fortgeschrittenem Rektumkarzinom
Wissenschaftl. Titel	Präoperative Radiochemotherapie und postoperative Chemotherapie mit Capecitabin und Oxaliplatin vs. Capecitabin beim lokal fortgeschrittenem Rektumkarzinom
Kurztitel	PETACC-6
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Darmkrebs (Kolorektales Karzinom): Erstlinie
Ziele	- Disease-free survival - Overall survival within at least the first 5 years after treatment - Loco-regional failure, defined as local or regional recurrence, inoperable disease, or R1 or R2 resection - Distant failure (i.e., distant metastasis) - Pathological down-stage (ypT0, 2N0) rate - Pathological complete remission (ypT0N0) rate - Tumor regression grade - Histopathological R0 resection rate - Sphincter preservation rate - Preoperative complication rate - Toxicity according to CTCAE v.3.0 weekly during treatment, at 4-8 weeks after surgery, at therapy completion, and every 6 months for 5 years after therapy completion
Einschlusskriterien	- DISEASE CHARACTERISTICS: - Histologically confirmed adenocarcinoma of the rectum - Tumor 12 cm from the anal verge - Stage T3-4 or any node-positive disease - No evidence of metastatic disease (confirmed by negative CT scan of the chest and abdomen) - Resectable disease or expected to become resectable after preoperative chemoradiation - May only be randomized once in this trial - PATIENT CHARACTERISTICS: - WHO/ECOG performance status 0-2 - Hemoglobin 10.0 g/dL (transfusion allowed to achieve or maintain levels) - ANC 1,500/mm^3 - Platelet count 100,000/mm^3 - ALT and AST 2.5 times upper level of normal (ULN) - Alkaline phosphatase 2.5 times ULN - Total bilirubin 1.5 times ULN - Creatinine clearance > 50 mL/min - Creatinine 1.5 times ULN - Able to swallow tablets - No prior or concurrent malignancies within the past 5 years except for adequately treated cone-biopsied carcinoma in situ of the cervix or basal cell carcinoma of the skin

- No clinically significant (i.e., active) cardiac disease, including any of the following:
- Congestive heart failure
- Symptomatic coronary artery disease
- Cardiac arrhythmia
- No myocardial infarction within the past 12 months
- No known significant impairment of intestinal resorption (e.g., chronic diarrhea, inflammatory bowel disease)
- No pre-existing conditions that would preclude chemoradiotherapy or radiotherapy (i.e., fistulas, severe ulcerative colitis [particularly patients currently taking sulfasalazine], Crohn's disease, or prior adhesions)
- No peripheral neuropathy grade 2 by CTCAE v3.0
- No serious uncontrolled intercurrent infections or other serious uncontrolled concomitant disease
- No history of uncontrolled seizures, central nervous system disorders or psychiatric disability that, in the opinion of the principal investigator, is clinically significant and would preclude giving informed consent or interfere with compliance with oral drug administration
- No psychological, familial, sociological, or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
- Not pregnant or nursing
- Fertile patients must use effective contraception
- PRIOR CONCURRENT THERAPY:
- No prior cytotoxic chemotherapy or radiation therapy for rectal cancer
- No prior radiation therapy to the pelvis
- No prior or concurrent investigational drug, agent, or procedure
- More than 4 weeks since prior participation in the active or follow-up period of another investigational protocol
- No known allergy or any other adverse reaction to any of the study drugs or to any related compound
- No known dihydropyrimidine dehydrogenase deficiency
- No organ allograft requiring immunosuppressive therapy
- No concurrent sorivudine or chemically related analogues (e.g., brivudine)

Alter	18 Jahre und älter
Sponsor	European Organization for Research and Treatment of Cancer (Hauptsponsor) Geron Corporation
Förderer	European Organization for Research and Treatment of Cancer Geron Corporation
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT00766155 (primäres Register) EudraCT 2006-006532-21
Therapie	Capecitabin, Oxaliplatin