KURZPROTOKOLL
CAO/ARO/AIO-16

Öffentlicher Titel	Phase II Studie zum Organerhalt durch Radiochemotherapie bei lokal fortgeschrittenem Rektumkarzinom
Wissenschaftl. Titel	Organ preservation in locally advanced ractal cancer by radiochemotherapy followed by consolidation chemotherapy. A prospective Phase II Pilot Trial Trial of the GermanRectal cancer Study Group
Kurztitel	CAO/ARO/AIO-16
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Verdauung: Darmkrebs (Kolorektales Karzinom): neoadjuvant
Einschlusskriterien	- Male and female patients with histologically confirmed diagnosis of rectal cancer localized 0 – 12 cm from the anocutaneous line as measured by rigid rectoscopy (i.e. lower and middle third of the rectum) - Any MRI staged cT3 tumor with a minimal distance from the mesorectal fascia > 2 mm - Any cT1 cN+ or cT2 cN+ with nodal staging according to “SOP MRI” - Staging requirements: High-resolution, thin-sliced (i.e. 3mm) magnetic resonance imaging (MRI) of the pelvis is the mandatory local staging procedure - Cross-sectional imaging of the abdomen and chest to exclude distant metastases - Aged at least 18 years. No upper age limit - WHO/ECOG Performance Status <= 1 - Adequate hematological, hepatic, renal and metabolic function parameters: Leukocytes >= 3.000/mm^3; ANC >= 1.500/mm^3; Platelets >= 100.000/mm^3; Hb > 9 g/dl; Serum creatinine <= 1.5 x upper limit of normal; Bilirubin <= 2.0 mg/dl, SGOT-SGPT, and AP <= 3 x upper limit of normal - Informed consent of the patient
Ausschlusskriterien	- Lower border of the tumor localised more than 12 cm from the anocutaneous line as measured by rigid rectoscopy - cT4 tumors - Positive lateral pelvic lymph nodes (s. SOP MRI) - Distant metastases (to be excluded by CT scan of the thorax and abdomen) - Preexisting fecal incontince for solid stool - Prior antineoplastic therapy for rectal cancer - Prior radiotherapy of the pelvic region - Major surgery within the last 4 weeks prior to inclusion - Subject pregnant or breast feeding, or planning to become pregnant within 6 months after the end of treatment - Subject (male or female) is not willing to use highly effective methods of contraception (per institutional standard) during treatment and for 6 months (male or female) after the end of treatment (adequate: oral contraceptives, intrauterine device or barrier method in conjunction with spermicidal jelly) - On-treatment participation in an interventional clinical study in the period 30 days prior to inclusion - Previous or current drug abuse - Other concomitant antineoplastic therapy - Serious concurrent diseases, including neurologic or psychiatric disorders (incl. dementia and uncontrolled seizures), active, uncontrolled infections, active, disseminated coagulation disorder

	- Clinically significant cardiovascular disease (incl. myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) 6 months before enrolment - Chronic diarrhea (> grade 1 according NCI CTCAE) - Prior or concurrent malignancy <= 3 years prior to enrolment in study (Exception: non -melanoma skin cancer or cervical carcinoma FIGO stage 0-1), if the patient is continuously disease-free - Known allergic reactions on study medication - Known dihydropyrimidine dehydrogenase deficiency - Psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule (these conditions should be discussed with the patient before registration in the trial)
Alter	18 Jahre und älter
Prüfzentren	**Strahlentherapie** (Rekrutierung beendet) Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Claus Rödel studien-strahlen@unimedizin-ffm.de **Universitätsklinikum Frankfurt** (Rekrutierung beendet) Klinik für Strahlentherapie und Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Claus Rödel studien-strahlen@unimedizin-ffm.de
Sponsor	Universitätsklinikum Tübingen
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