

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 rectal cancer by radiochemotherapy followed by consolidation chemotherapy. A prospective Phase II Pilot Trial of the German Rectal 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	<ul style="list-style-type: none">- 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/mm³; ANC >= 1.500/mm³; Platelets >= 100.000/mm³; 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	<ul style="list-style-type: none">- 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 incontinence 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

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- 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	Universitätsklinikum Frankfurt (Rekrutierung beendet) Klinik für Strahlentherapie und Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Claus Rödel studien-strahlen@kgu.de
Sponsor	Universitätsklinikum Tübingen
Registrierung in anderen Studienregistern	EudraCT 2017-003057-42