KURZPROTOKOLL
TopRoc

Öffentlicher Titel	Adjuvante Erstlinien-Radiochemotherapie bei Mundrachenkrebs
Wissenschaftl. Titel	Comparative Effectiveness Trial of Transoral Head and Neck Surgery followed by adjuvant Radio(chemo)therapy versus primary Radiochemotherapy for Oropharyngeal Cancer
Kurztitel	TopRoc
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Kopf-Hals: Kopf-Hals-Tumoren: adjuvant
Einschlusskriterien	- Histologically proven SCC of the oropharynx; clinical stage III-IVA (T1, N2a-c, M0; T2, N1-2c, M0; T3, N0-2c, M0, with only amendable to transoral resection) - Primary tumor must be resectable through transoral approach - FFPE tissue must be available for central HPV diagnostic - Written and signed informed consent - Briefing through surgeon and radiation oncologist - ECOG PS >=2, Karnofsky PS >= 60 % - Age >= 18 - Curative treatment intent - Adequate bone marrow function: leucocytes > 3.0 x 109/L, neutrophils > 1.5 x 109/L, platelets > 80 x 109/L, hemoglobin > 9.5 g/dL - Adequate liver function: Bilirubin < 2.0 g/dL, SGOT, SGPT, < 3 x ULN - If of childbearing potential, willingness to use effective contraceptive method for the study duration and 2 months post-dosing. - All patients require: - 1. dental examination and appropriate dental therapy if needed prior to the beginning of radiotherapy - 2. Nutritional evaluation prior to the initiation of therapy and optional prophylactic gastrostomy (PEG) tube placement
Ausschlusskriterien	- Prior invasive malignancy except controlled skin cancer or carcinoma in situ of cervix - Unknown primary (CUP), nasopharynx, hypopharynx, laryngeal or salivary gland cancer - Metastatic disease - Serious co-morbidity, e.g. high-grade carotid artery stenosis, congestive heart failure NYHA grade 3 and 4, liver cirrhosis CHILD C - Hemoglobin level <9.5g/dl within 10 days before randomization - Pregnancy or lactation - Women of child-bearing potential with unclear contraception - Previous treatment with chemotherapy, radiotherapy, EGFRtargeting agents or surgery exceeding biopsy in head and neck - Concurrent treatment with other experimental drugs or participation in another clinical trial with any investigational drug within 30 days prior to study screening - Social situations that limit compliance with study requirements or patients with an unstable condition (e.g., psychiatric disorder, a recent history of drug or alcohol abuse, interfering with study compliance, within 6 months prior to screening) or otherwise thought to be unreliable or incapable of complying with the requirements of the protocol - Patients institutionalized by official means or court order

	- Deficient dental preservation status or not accomplished wound healing groups.
Alter	18 Jahre und älter
Prüfzentren	**Strahlentherapie** (Rekrutierung beendet) Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Claus Rödel studien-strahlen@kgu.de **Universitätsklinikum Gießen und Marburg, Standort Gießen** (Aktiv) Hals-, Nasen- und Ohrenheilkunde Rudolf-Buchheim-Straße 8 35392 Gießen Dr. med. Christine Langer Tel: 00641 98543701 **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 Eppendorf
Förderer	Deutsche Krebshilfe e.V.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03691441 (primäres Register) EudraCT 2016-002163-34