

## **KURZPROTOKOLL** **TopRoc**

<b>Öffentlicher Titel</b>	Adjuvante Erstlinien-Radiochemotherapie bei Mundrachenkrebs
<b>Wissenschaftl. Titel</b>	Comparative Effectiveness Trial of Transoral Head and Neck Surgery followed by adjuvant Radio(chemo)therapy versus primary Radiochemotherapy for Oropharyngeal Cancer
<b>Kurztitel</b>	TopRoc
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Kopf-Hals: Kopf-Hals-Tumoren: adjuvant
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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)</li><li>- Primary tumor must be resectable through transoral approach</li><li>- FFPE tissue must be available for central HPV diagnostic</li><li>- Written and signed informed consent</li><li>- Briefing through surgeon and radiation oncologist</li><li>- ECOG PS <math>\geq 2</math>, Karnofsky PS <math>\geq 60\%</math></li><li>- Age <math>\geq 18</math></li><li>- Curative treatment intent</li><li>- Adequate bone marrow function: leucocytes <math>&gt; 3.0 \times 10^9/L</math>, neutrophils <math>&gt; 1.5 \times 10^9/L</math>, platelets <math>&gt; 80 \times 10^9/L</math>, hemoglobin <math>&gt; 9.5 \text{ g/dL}</math></li><li>- Adequate liver function: Bilirubin <math>&lt; 2.0 \text{ g/dL}</math>, SGOT, SGPT, <math>&lt; 3 \times \text{ULN}</math></li><li>- If of childbearing potential, willingness to use effective contraceptive method for the study duration and 2 months post-dosing.</li><li>- All patients require:<ol style="list-style-type: none"><li>1. dental examination and appropriate dental therapy if needed prior to the beginning of radiotherapy</li><li>2. Nutritional evaluation prior to the initiation of therapy and optional prophylactic gastrostomy (PEG) tube placement</li></ol></li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Prior invasive malignancy except controlled skin cancer or carcinoma in situ of cervix</li><li>- Unknown primary (CUP), nasopharynx, hypopharynx, laryngeal or salivary gland cancer</li><li>- Metastatic disease</li><li>- Serious co-morbidity, e.g. high-grade carotid artery stenosis, congestive heart failure NYHA grade 3 and 4, liver cirrhosis CHILD C</li><li>- Hemoglobin level <math>&lt; 9.5 \text{ g/dl}</math> within 10 days before randomization</li><li>- Pregnancy or lactation</li><li>- Women of child-bearing potential with unclear contraception</li><li>- Previous treatment with chemotherapy, radiotherapy, EGFRtargeting agents or surgery exceeding biopsy in head and neck</li><li>- Concurrent treatment with other experimental drugs or participation in another clinical trial with any investigational drug within 30 days prior to study screening</li><li>- 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</li><li>- Patients institutionalized by official means or court order</li></ul>

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