



Fondation du Centre  
Pluridisciplinaire d'Oncologie

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CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

### ZOOM SAKK 75/08

<b>Indication</b>	<b>GI-Esophageal:</b> locally advanced esophageal carcinoma
<b>Title</b>	Multimodal therapy with and without cetuximab in patients with locally advanced esophageal carcinoma. An open-label phase III trial.
<b>Protocol ID</b>	<b>SAKK 75/08</b>
<b>Phase</b>	<b>Phase III</b>
<b>Sponsor</b>	SAKK (Swiss Group for Clinical Cancer Research)
<b>Local Principal Investigator</b>	Dr A. Dorothea WAGNER
<b>Primary Objective</b>	The primary objective of the trial is to determine the efficacy of neoadjuvant radiochemotherapy (RCT) combined with immunotherapy followed by adjuvant immunotherapy compared with the same schedule without immunotherapy.
<b>Inclusion/exclusion criteria</b>	<p><b>Inclusion Criteria include the following :</b></p> <ul style="list-style-type: none"> <li>○ Histologically confirmed squamous cell carcinoma (including basaloid-squamous cell and adenosquamous carcinoma) or adenocarcinoma of the thoracic esophagus or the esophagogastric junction (from 5 cm below the entrance of the esophagus into the thorax to the gastric cardia (=esophagogastric junction), types I and II according to the Siewert classification).</li> <li>○ Resectable, locally advanced disease (the stage is determined by the combination of CT scan, EUS and PET and by a multidisciplinary team discussion):- T2 N1-3 or T3 Nany or T4a Nany if technically resectable with curative intent (R0) as decided by a multidisciplinary team discussion</li> <li>○ Patient must give written informed consent before randomization and prior to any trial specific procedures</li> <li>○ EQ-5D questionnaire and BL-HEA form were completed within 14 days before randomization (applicable for Swiss centers and for patients who gave consent for the HEA only)</li> <li>○ Age: 18-75 years</li> <li>○ Health status: WHO performance status (PS) <math>\leq</math> 1</li> <li>○ Patient is considered operable (appropriate organ functions, ability to undergo general anesthesia)</li> <li>○ Adequate hematologic, renal, hepatic, pulmonary function</li> <li>○ Patient compliance and geographic proximity allow proper staging and follow-up.</li> <li>○ Women are not breastfeeding, are using effective</li> </ul>

contraception

- Men agree not to father a child during participation in the trial and during the twelve months thereafter.
- The responsible pathologist is informed to provide sample material (only if the patient gave informed consent for biobanking).

**Exclusion criteria include the following :**

- Stage T1 Nany M0, Stage T2 N0 M0, Stage T4a due to infiltration of the tracheo-bronchial tree or organ involvement which cannot be operated on with curative intent (R0) as decided by a multidisciplinary team discussion, Stage T4b
- Distant metastasis (M1)
- Cervical esophageal carcinoma and tumors involving the first 5 cm of the thoracic esophagus
- Airway infiltration in case of tumors at or above the tracheal bifurcation
- Previous malignancies within five years or concomitant malignancies, except: nonmelanomatous skin cancer or adequately treated in situ cervical cancer
- Prior chemotherapy or prior RT to the chest
- Severe or uncontrolled cardiovascular disease (congestive heart failure NYHA III or IV, unstable angina pectoris, history of myocardial infarction within the last twelve months, significant arrhythmias)
- Psychiatric disorder precluding understanding of information on trial related topics, giving informed consent and answering the questions of the EQ-5D questionnaire and HEA forms
- Active uncontrolled infection
- Serious underlying medical condition (judged by the investigator) which could impair the ability of the patient to participate in the trial (e.g. uncontrolled diabetes mellitus, active autoimmune disease)
- Preexisting peripheral neuropathy (> grade 1)
- Concurrent treatment with other experimental drugs or other anti-cancer therapy; treatment in a clinical trial within 30 days prior to trial entry
- Definite contraindications for the use of corticosteroids and antihistamines as premedication
- Known hypersensitivity to trial drugs or hypersensitivity to any other component of the trial drugs
- Any concomitant drugs contraindicated for use with the trial drugs according to the product information of the pharmaceutical companies