



Fondation du Centre
Pluridisciplinaire d'Oncologie

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CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

ZOOM SAKK 16/00

Indication	NSCLC, Stade IIIA
Title	Preoperative chemoradiotherapy vs. chemotherapy alone in non-small cell lung cancer (NSCLC) patients with mediastinal lymph node metastases (stage IIIA, N2): A randomized prospective phase III trial
Protocol ID	SAKK 16/00
Phase	Phase III
Sponsor	SAKK (Swiss Group for Clinical Cancer Research)
Local Principal Investigator	Dr. R. Stupp
Primary Objective	<p>The main objective of this trial is to compare feasibility and efficacy of sequential neoadjuvant chemoradiotherapy with 44 Gy concomitant boost to neoadjuvant chemotherapy alone.</p> <p>Secondary objectives are to assess the value of PET in predicting pathological response and event-free survival in stage IIIA NSCLC, and an economic evaluation of the two regimens.</p> <p>Further to compare the amount of serum DNA in patients with stage IIIA, pN2 NSCLC before, during and after chemotherapy, before and after radiotherapy (in arm A) and during follow-up in patients randomized into the trial SAKK 16/00 and to correlate the DNA variation with tumor response, remission duration and overall survival.</p>
Inclusion/exclusion criteria	<p>Inclusion Criteria include the following :</p> <ul style="list-style-type: none"> ○ Histologically proven NSCLC (squamous, adeno-, large cell or poorly differentiated NSCLC) with nodal metastases: T1-3N2M0 (TNM definitions see appendix IV); N2 disease stage proven by one of the following procedures: <ul style="list-style-type: none"> Procedure 1: Mediastinoscopy (see section 10.2.1) or Procedure 2: N2 can be histologically or cytologically proven by other means than mediastinoscopy (e.g. bronchoscopy with FNA or esophagoscopy, etc) AND all N3 lymph nodes are negative in the PET AND all N3 lymph nodes are negative in the CT scan (< 1 cm in the largest diameter) Procedure 3: If there is histological/cytological proof of NSCLC (e.g. from the primary tumor), but the N2 lymph nodes CANNOT be biopsied by mediastinoscopy or any other means (e.g. aortic nodes region 5 & 6) AND both the primary tumor and at least one N2 lymph node which cannot be biopsied is positive in PET AND At least one of the

PET positive N2 lymph nodes is positive in the CT scan (measures > 1 cm in the largest diameter in the CT scan) **AND** all N3 lymph nodes are negative in PET

- Operability: appropriate lung function and normal cardiac function according to local standards
- WHO-Performance status 0-1
- Normal liver, bone marrow and renal functions
- Age 18-75

Exclusion criteria include the following :

- Patients with prior or concomitant malignancies Allowed are: non-melanomatous skin cancer, adequately treated in situ cervical cancer or any other neoplastic diseases with disease-free interval ≥ 5 years.
- Presence or history of any distant metastasis
- Unstable cardiac disease requiring treatment, congestive heart failure or angina pectoris even if medically controlled, significant arrhythmia, or prior history of myocardial infarction in the last 3 months
- History of significant neurologic or psychiatric disorders including psychotic disorders, dementia or seizures that would prohibit the understanding and giving of informed consent
- Active uncontrolled infection
- Uncontrolled diabetes mellitus
- Gastric ulcers
- Preexisting peripheral neuropathy (> grade 1)
- Other serious underlying medical condition which could impair the ability of the patient to participate in the trial
- Concurrent treatment with other experimental drugs
- Pretreatment with any other cytostatic therapy
- Previous radiotherapy to the chest
- Concurrent treatment with prednisone (or equivalent) except: for the prophylactic medication regimen before treatment, treatment of acute hypersensitivity reactions or chronic treatment (initiated > 6 months prior to trial entry) at low dose (≤ 20 mg methylprednisolone or equivalent)
- Definite contraindications for the use of corticosteroids as premedication
- Treatment within a clinical trial within 30 days prior to trial entry
- Socioeconomic or geographic circumstances that may prohibit proper staging, treatment or follow-up procedures
- Pregnancy, lactation period