Département d'oncologie
Plateformes du DO
Bâtiment Maternité PAV1
Avenue Pierre Decker 2
CH-1011 Lausanne

Indication	**Tumeurs germinales**, séminomes
Title	Carboplatin chemotherapy and involved node radiotherapy in stage IIA/B seminoma.
Protocol ID	**SAKK 01/10**
Phase	Phase II
Sponsor	SAKK (Swiss Group for Clinical Cancer Research)
Local Principal Investigator	Dr Dominik Berthold
Primary Objective	The main objective of this trial is to test the efficacy and safety of carboplatin chemotherapy and involved node radiotherapy in patients with stage IIA/B seminoma.
Inclusion/exclusion criteria	**Inclusion Criteria include the following :** • Patient has given written informed consent before registration. • Histologically confirmed classical seminoma treated with primary inguinal orchidectomy 12 weeks or less before registration. • Tumor stage is pT1-4 cN1-2 cM0 according to UICC TNM 2009 • Multi-slice CT of the chest, abdomen and pelvis or a FDG-PET-CT within 4 weeks prior to patient registration, showing stage IIA/B disease. Oral and i.v. contrast have to be administered. • Age ≥ 18 years. • WHO performance status 0-2. • Adequate hematological values: neutrophils ≥ 1.0 x 109/L, platelets ≥ 100x 109/L. • Adequate renal function (calculated creatinine clearance ≥ 50 ml/min, according to the formula of Cockcroft-Gault). • Patient agrees not to father a child during trial treatment and during 12 months thereafter. • Patient has been proposed sperm conservation. • Patient compliance and geographic proximity allow proper staging and follow-up for at least 3 years. **Exclusion Criteria include the following:** • Previous or concurrent malignancy within 5 years with the exception of localized non-melanoma skin cancer. • Psychiatric disorder precluding understanding of information on trial-related topics or giving informed consent or interfering with compliance for treatment schedule. • Mixed histology seminoma. • Elevated levels of AFP (≥ULN). • Any prior abdominal/pelvic radiotherapy.

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	• Any anti-cancer therapy after primary tumor resection. • Any treatment in a clinical trial within 30 days of trial entry. • Any serious underlying medical condition or serious co-morbidity (at the judgment of the investigator) which could impair the ability of the patient to participate in the trial. • Any contraindication for the trial drug (for example, known hypersensitivity to trial drug or to any other co-component of the trial drug, past or current renal insufficiency, severe hepatic insufficiency, severe bone marrow dysfunction, tumor bleeding, major hearing defects). • Any concomitant drugs contraindicated for use with the trial drug according to the approved product information (for example, nephrotoxic or ototoxic medicines).