

Results of trial SAKK 01/10: Mild chemotherapy followed by reduced radiotherapy just as effective, but tolerated much better than conventional treatment by seminoma patients

Thank you

Thank you very much for taking part in the still ongoing trial SAKK 01/10. You are helping us to find answers to important questions about the treatment of testicular cancer. As a result, we will be able to offer future patients better treatments with fewer side effects.

This summary has been written at the start of 2023 and presents the key results of the trial.

What is trial SAKK 01/10 all about?

Seminomas are malignant testicular tumors, which constitute one of the most common types of cancer in men under 40. Around 470 men in Switzerland develop testicular cancer each year. In roughly 15% of patients the tumor is discovered when it has already formed secondaries (known as metastases) in the lymph nodes in the abdomen and pelvis. Depending on the size of the affected lymph nodes, the tumor is either in stage IIA or IIB.

Conventional treatments for patients with a seminoma in stages IIA/B consist either of comprehensive radiotherapy or intensive chemotherapy

with three different drugs. Both treatments prove successful in over 90% of patients, but unfortunately they are often associated with serious side effects. They can also cause long-term damage to blood vessels, kidneys, intestines or the inner ear.

In trial SAKK 01/10 we have investigated a new therapeutic approach – in the hope that it will prove just as effective, but will be tolerated much better than the conventional treatments.

What about this new treatment that we have investigated?

The new therapeutic approach is a combined treatment including, on the one hand, the administration of carboplatin, a drug used in the treatment of many different types of tumors and that is usually very well tolerated.

On the other hand, the treatment also consists of radiotherapy targeted on the affected lymph nodes and which therefore manages with just a quarter of the radioactive exposure compared to traditional radiotherapy.



Who has taken part in trial SAKK 01/10?

Between October 2012 and June 2018, we enrolled a total of 120 patients from Switzerland and Germany in the trial. They were aged between 22 and 68 and had a median of two affected lymph nodes measuring between 1.5 and 3.3 cm across.

We have treated 116 of the 120 patients within the trial. In 4 patients, the investigations before treatment revealed that the seminoma had not yet reached stage IIA or IIB, or that kidney function was impaired. We had to exclude these patients from the trial – and subsequently treat them outside the trial.

What are the results of trial SAKK 01/10?

Three years after enrollment in the trial, the testicular cancer had not recurred in 109 (94%) of the patients. Only 7 patients (6%) suffered from a progression of the disease and we managed to treat them all successfully with standard chemo-

therapy. Most cases with disease progression occurred within the first two years after being recruited to the trial.

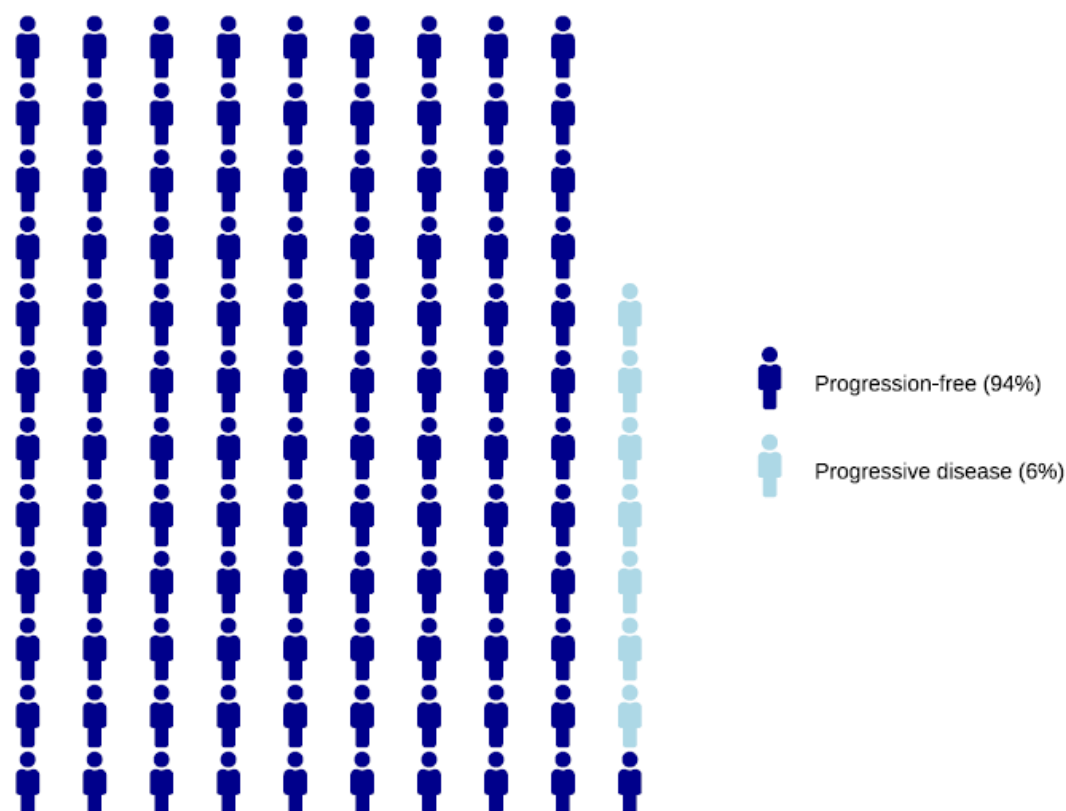


Figure: status of the disease three years after enrollment



30 (21%) and 22 (19%) patients, respectively, experienced mild and moderate side effects of the chemotherapy. Only 6 patients (5%) suffered

moderate or severe blood count changes during the treatment. Fortunately, we have not observed any longer-term adverse effects in any patient.

	Mild side effect	Moderate side effect	Serious side effect
Nausea	31		
Fatigue	29		
Diarrhea	11		
Blood count changes	7	5	1
Loss of appetite	6		
Headache	6		
Vomiting	5	1	

Table: Acute, treatment-related side effects occurring in more than 5% of participants. The table shows the number of individuals affected per side effect and their severity.

What do these results mean?

The trial shows that the new combined therapeutic approach is just as effective as the conventional treatments. Whereas the mild chemotherapy prevents the formation of remote secondaries, the reduced radiotherapy ensures that the secondaries in the abdominal or pelvic lymph nodes disappear.

Overall, the new combination of chemotherapy and radiotherapy causes far fewer side effects –

and is therefore much better tolerated than the conventional treatments. At the same time, the new and less intensive therapeutic approach is also associated with a lower risk of long-term effects and the development of secondary tumors. In our view therefore, the results of our trial signify a definite advance in the treatment of testicular cancer.

What now?

The trial is not yet concluded, since the patients are being followed up for up to 20 years after completing the treatment. Nevertheless, we have already put in place a successor trial that builds on the results of this trial. In the trial SAKK 01/18, we are investigating whether we can reduce the

intensity of the chemotherapy and radiotherapy still further.

Further information

Please contact your doctor if you have any questions. The trial results have been published in the specialist journal [The Lancet Oncology](#). The original title of the trial: "Single-dose carboplatin followed by involved-node radiotherapy

for stage IIA and stage IIB seminoma (SAKK 01/10): a single-arm, multicentre, phase 2 trial". All currently open clinical trials are listed on the website of the Swiss Group for Clinical Cancer Research (SAKK) www.sakk.ch.