

Results of trial SAKK 16/14: Neoadjuvant immunotherapy in locally advanced non-small cell lung cancer

Thank you

Thank you very much for taking part in trial SAKK 16/14.

You are helping us to find answers to important questions about the treatment of locally advanced non-small cell lung cancer. As a result, we hope to be able to offer future patients better treatments.

This summary was written in October 2023. The trial is continuing until 2025.

What is this trial about?

Patients who suffer from locally advanced non-small cell lung cancer are treated with chemotherapy followed by surgery.

Unfortunately, the cancer returns in slightly more than half of the patients within the first year of diagnosis.

In trial SAKK 16/14 we want to find out whether **immunotherapy administered in addition** to the standard treatment can improve the prognosis for the patients. We also want to see how well this additional therapy is tolerated.

What is the treatment that we have investigated?

The immunotherapy consists of the active substance **durvalumab** and is administered **before and after the surgery**.

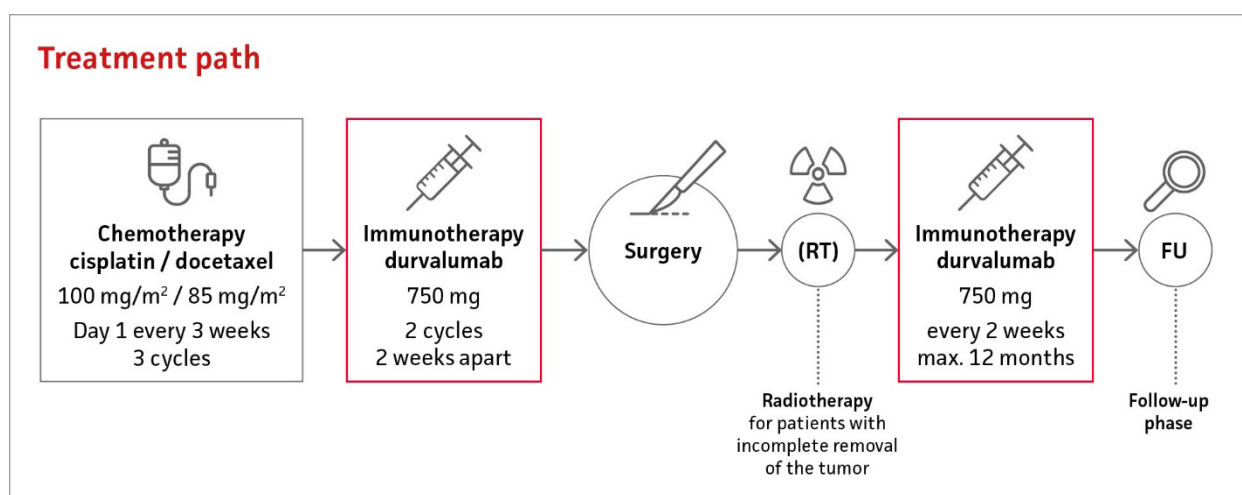
Durvalumab is an antibody that improves the ability of the body's own immune system to combat the cancer. Such antibodies have proved to be beneficial in various cancers.

In this trial we are investigating, for the first time, whether this treatment can be helpful in locally advanced lung cancer.



The detailed trial treatment is as follows:

- 2 to 4 weeks **before the operation** (and after the usual three cycles of chemotherapy), **two cycles of 750 mg durvalumab** in each case are administered 2 weeks apart
- 2 to 4 weeks after the last dose of durvalumab, the tumor is surgically removed. If the tumor cannot be removed completely, radiotherapy is administered.
- 2 to 4 weeks **after the operation** the participants receive **750 mg durvalumab every 2 weeks**. The treatment is administered for one year.



Who takes part in the trial?

35 men and 32 women aged from 41 to 72 from a total of 14 hospitals in Switzerland take part in this trial.

- Half of the 67 patients were older than 61 at the beginning of the trial.
- All are suffering from locally advanced, operable non-small cell lung cancer.
- All 67 patients are considered to be patients with a high risk of recurrence.

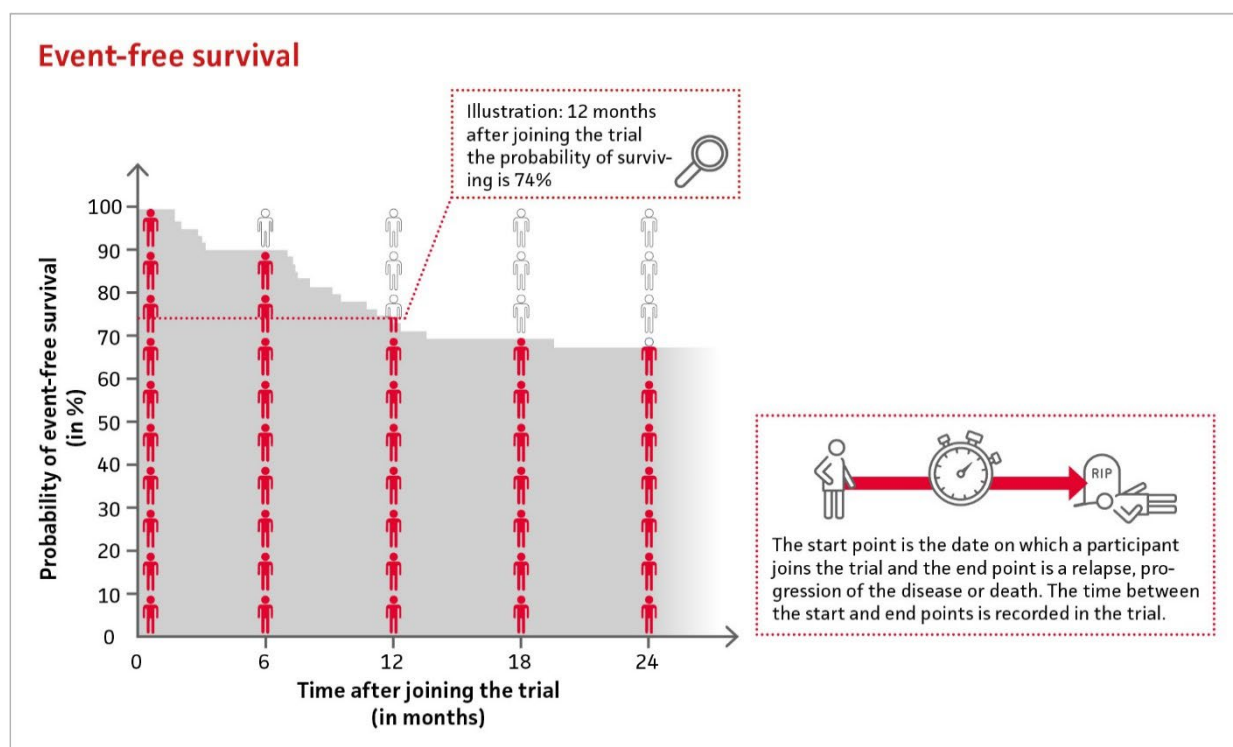


What are the results of the trial?

After we have followed up the participants for a median¹ period of **29 months**, the results are as follows:

- Of the 67 participants, 45 are still alive and have not had a recurrence of the cancer.
- 15 of the 67 participants have died.
- In 12 of the 15 patients who died, the cause of death was a recurrence of the lung cancer.

If this is extrapolated to 100 participants by statistical methods, this means that 73 of 100 patients have **not** suffered a recurrence. In the comparable trial 16/00, in which no additional immunotherapy was administered, only 48 of 100 participants **did not** suffer a recurrence.



¹ Median means that half of the participants were above and half below this figure



Moreover, the additional administration of the immunotherapy was just as safe as the standard treatment.

- All 67 patients experienced side effects during the trial treatment
- Severe side effects were experienced by 59 participants (including 2 with a fatal outcome, of which one was thought to be due to the cancer)

- Side effects that were attributable to the immunotherapy itself were pneumonitis (2 participants), allergic reactions (3 participants) and hepatic function abnormalities (6 participants)

What do these results mean?

Trial SAKK 16/14 shows a distinct improvement in the prognosis for the patients. Since these results are better than expected, this therapeutic method is to be further investigated.

The trial also shows that this treatment can be used safely.

What now?

The trial is continuing until 2025. This means that the participants will continue to be followed up. We are also collecting blood and stool samples, and the corresponding laboratory tests should

give us a better understanding of the mode of action of the medication and the differing responses to the treatment.

Further information

Please contact your doctor if you have any questions.

The trial results have been published in the [Journal of Clinical Oncology](#). The original English title of the trial is "SAKK 16/14: Durvalumab in Addition to Neoadjuvant Chemotherapy in Patients With Stage IIIA(N2) Non-Small-Cell Lung Cancer – A Multicenter Single-Arm Phase II Trial".

All currently open clinical trials are listed on the website of the Swiss Group for Clinical Cancer Research (SAKK) www.sakk.ch.