

Clinical trial summary (S1925)

Testing Early Treatment for Patients with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)



What is the purpose of this clinical trial?

The purpose of this trial is to find out if people with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) will live longer and have a better quality of life if they start treatment earlier. Some people do not have major symptoms when they are diagnosed with CLL or SLL. Treatment is often started when they show symptoms such as fever, anemia, or night sweats. Studies show that early treatment using older chemotherapy drugs doesn't help people live longer or better compared to later treatment. In this trial, researchers want to find out if early treatment with newer, more targeted cancer drugs will help patients live longer and

improve their quality of life. To learn this, they will compare outcomes in early and later treatment groups.

This trial is set up to find out:

- How long participants survive with early treatment compared to later treatment
- How long participants' cancer responds to early treatment compared to later treatment
- Whether participants have side effects from the study drugs
- How participants feel about the quality of their lives in terms of mood, pain, and other factors



Why is this trial important?

Instead of waiting until they have symptoms, many patients with CLL or SLL want to be treated as soon as possible. Doctors want to test whether early treatment with new drugs can help patients with CLL or SLL live longer, keep their cancer from returning quickly, and improve their quality of life.

CLL is the most common leukemia in adults, and many patients are too old or frail to take chemotherapy drugs or get stem cell transplants. They need different treatment options. Because the newer cancer drugs have fewer side effects, this trial provides an option for these patients.



Who can be in this trial?

This trial is for men and women over the age of 18 who have been diagnosed with CLL or SLL in the last 12 months and have no significant symptoms. They must be considered "high risk" by their doctors.

This trial may be right for people who:

- Have been diagnosed with their cancer within the last 12 months
- Have not received any therapy for their cancer
- Are at higher risk for their cancer growing and spreading based on a medical test score

This trial is not for people who:

- Have already been treated for CLL or SLL
- Have poorly functioning kidneys or liver
- Have untreated HIV, an active hepatitis B or C infection, a bleeding disorder, or a history of stroke



What treatments would I get?

If you join the trial, you will be randomly assigned into one of 2 groups. One group will start treatment right away with the new drugs. These drugs are obinutuzumab, a liquid medicine given by injection once a month for 6 months, and venetoclax, a pill taken each day for one year. The other group will receive the same new drugs, but only after symptoms appear. Both new drugs are approved by the Food and Drug Administration (FDA) to treat CLL and SLL.

Note: Your doctor will not have control over which group you are assigned to. This helps make sure the trial results are fair and reliable.



How long will I be in the trial?

You will take the study drugs for one year. You will have regular tests and health checks for a total of 10 years.



Are there costs to join the trial? Will I get paid?

The companies that make the trial drugs will pay for the drugs. Insurance companies often pay for standard of care treatments, like visits and cancer scans. Check with your healthcare and insurance providers to find out what costs will and will not be covered. You will not be paid for joining the study.



Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to www.ClinicalTrials.gov and search using the national clinical trial number: **04269902**



Key information *This trial is for adults 18 years or older being*

Protocol number: S1925

NCT number: 04269902

Full trial title: Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia / Small

Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study

Other trial names: EVOLVE CLL/SLL Study

Trial sponsors: SWOG Cancer Research Network and ECOG-ACRIN Cancer Research Group with support from Genentech and AbbVie.

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Thank you!

When you participate in a clinical trial, you're moving cancer medicine and patient care forward.