A Hematology Study

Testing early treatment for patients with chronic lymphocytic leukemia or small lymphocytic lymphoma

CLC.3 | NCT04269902

What is the purpose of this study?

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 have shown that early treatment using older chemotherapy drugs doesn't improve outcomes 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.

Why is this study 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 participate in this study?

This trial is for:

- Women and men over the age of 18 who have been diagnosed with CLL or SLL and have no significant symptoms.
- People who are considered "high risk" by their doctors.
- People diagnosed with their cancer within the last 12 months.
- People who have not received any therapy for their cancer.
- People 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.
- People who have poorly functioning kidneys or liver.
- People who have untreated HIV, an active hepatitis B or C infection, a bleeding disorder, or a recent stroke.

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SHARE THIS SUMMARY WITH YOUR **HEALTH CARE TEAM**
TO SEE IF THIS TRIAL IS A GOOD OPTION FOR YOU.

What are the risks?

If you choose to take part in this study, there is a risk that the study approach (treating patients early) may not be as good as the usual approach (treating patients after symptoms start). There is also a risk that you could have side effects from the study approach. Some of the most common side effects that the study doctors know about are: Reaction to the infusion which may include nausea, headache, fever and chills, increased infection risk, tiredness, increased bleeding risk, and a decrease in the number of red blood cells (anemia). You will find details of all side effects in the consent document.

What can I expect?

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. The other group will receive the same new drugs, but only after symptoms appear.

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.

In this study, you will also be asked to complete a few questionnaires at different times, to understand your Quality of Life.

How can I find out more or join the study?

Talk to your cancer doctor if you are considering joining this study. You can share summaries like this with them and ask if they think joining the trial may be a good option for you.

Before you join this study, you will be asked to review an *Informed Consent* document which will tell you more about why the research is being done and your role as a participant. You will have an opportunity to discuss anything that is not clear and ask any questions you have.

Joining this study is entirely up to you and you can decide to leave at any time without giving a reason. Your decision to join or leave the trial will not affect your standard medical care.

The **CLC.3 study** is currently enrolling patients at cancer centres in Canada. For a full list of participating cancer centres please visit www.clinicaltrials.gov and search using NCT04269902. Direct link: https://clinicaltrials.gov/ct2/show/NCT04269902

{for participating Centre's use - contact information, enrollment instructions, logo}