A Hematology Clinical Trial

Targeted therapy for patients with early-stage Hodgkin lymphoma HD12 | NCT04685616

What is the purpose of this study?

The purpose of this study is to compare the usual treatment for your Hodgkin lymphoma, which is a standard combination of four drugs, versus the standard combination with one drug of the combination replaced with a new drug that we hope will be more effective and cause you fewer side effects.

Why is this study important?

This new drug combination is being developed for the treatment of Hodgkin Lymphoma cancer. Laboratory tests show that it may help slow the growth of Hodgkin lymphoma cancer. This new drug combination has been studied in a few people and seems promising, but it is not clear if it can offer better results than standard combination treatment.

Who can participate in this study?

This trial is for:

• Reasonably healthy males and females aged 16-69 years with classical Hodgkin lymphoma

This trial is not for:

- Individuals who have already had treatment for their Hodgkin lymphoma cancer
- Individuals with infradiaphragmatic disease, which is disease found entirely below the diaphragm, or individuals with disease found both above and below the diaphragm
- A kind of Hodgkin lymphoma which is called nodular, lymphocyte predominant. This type of Hodgkin lymphoma is often treated differently to classical Hodgkin Lymphoma
- Individuals who have had other types of cancer within the last 5 years, except for skin cancer and carcinoma that has not spread
- Individuals with pre-existing conditions like chronic conditions of the brain, symptomatic nervous system disorders, bloodborne viruses like hepatitis B, heart or lung disease, or any other medical or psychiatric illness that would make treatment dangerous for the patient

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What are the risks?

If you choose to take part in this study, there is a risk that the new drug combination may not be as good as the standard combination treatment. There is also a risk that you could have side effects from the new drug combination. Some of the most common side effects that the study doctors know about are: diarrhea, nausea, tiredness, numbness, tingling or pain of the arms and legs. You will find details of all side effects in the consent document.

What can I expect?

If you choose to take part in this study, you will be randomly placed in one of two groups, and you will receive either the new drug combination or the standard drug combination which is commonly used to treat this disease. You will be told which group you are in.

In this study, you will also be asked to complete a few questionnaires at different times, to understand your quality of life, side effects, and financial costs of cancer and cancer treatment. There are also optional studies done using blood and tissue collected at different times that researchers hope will help other people with cancer in the future.

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 CCTG HD.12 study is currently enrolling patients at cancer centres in Canada and will enroll patients from select centres in the United States. For a full list of participating cancer centres please visit www.clinicaltrials.gov and search using NCT04685616.

