An endometrial cancer study

Tailoring therapy in post-surgical patients with endometrial cancer

CCTG EN.11 | NCT05255653

What is the purpose of this study?

The purpose of this study is to compare the effects on you and your endometrial cancer of a new drug in combination with radiation therapy compared to the current standard treatment of radiation therapy alone.

Why is this study important?

The new drug being studied is a new type of drug being developed for the treatment of one sub-type of endometrial cancer. Laboratory tests show that it may help slow the growth of endometrial cancer. The new drug has been studied in a few people and seems promising, but it is not clear if it can offer better survival and quality of life results than standard treatment.

Who can participate in this study?

This trial is for:

- Patients whose cancer has not spread to other areas of their body
- Patients who are 18 years of age or older
- Patients who are available for treatment and follow-up
- Patients who have not had previous radiation therapy treatment to the pelvis
- Patients who weigh more than 30 kg

This trial is not for:

- Patients who have had a previous diagnosis of cancer
- Patients who have had a previous organ transplant
- Patients who have an uncontrolled illness such as high blood pressure, lung disease, serious gastrointestinal conditions causing diarrhea, or psychiatric conditions that would limit the ability to take part in the trial safely
- Patients who are currently taking an immunosuppressive drug

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Canadian Cancer Trials Group
Groupe canadien des essais sur le cancer

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 new drug may not be as good as the standard treatment. There is also a risk that you could have side effects from the new drug. Some of the most common side effects that the study doctors know about are:

- fatigue/tiredness
- decreased or loss of appetite, which may result in weight loss
- cough
- inflammation of the small intestine and /or large bowel causing abdominal pain and diarrhea which may be severe

You will find the details of all potential side effects in the consent document that you review with your physician.

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 with radiation treatment, or you will receive radiation treatment alone, which is commonly used to treat this disease.

In this study, you will also be asked to complete a questionnaire at different times, to help the study team 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 CCTG EN.11 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 NCT05255653. https://www.clinicaltrials.gov/ct2/show/NCT05255653?term=rainbo&draw=2&rank=1