A rectal cancer clinical trial

Testing chemotherapy versus chemotherapy plus radiotherapy prior to limited surgery for early rectal cancer

CO.32 | NCT06205485

What is the purpose of this study?

The purpose of this study is to compare the usual approach of chemotherapy plus radiation therapy followed by limited surgery, to using a more intense combination chemotherapy treatment followed by limited surgery.

The study approach without radiation may improve your quality of life and be equally effective at shrinking or stabilizing your cancer.

Why is this study important?

This study will help the study doctors find out if this different approach is better, the same, or worse than the usual approach. The study doctors will be looking to see if the study approach of chemotherapy alone will treat your cancer as well as the usual approach while improving your quality of life.

Who can participate in this study?

This trial is for:

- Adults aged 18 and older
- Individuals with a specific early rectal cancer
- Individuals who are able to receive chemotherapy
- Individuals medically fit for limited surgery of their rectal cancer

This trial is not for:

- Pregnant individuals or individuals planning to become pregnant or who are of childbearing potential without reliable means of contraception
- Individuals previously treated for rectal cancer including radiation
- Individuals with a known history of heart problems
- Individuals who can not undergo MRI imaging

What are the risks?

If you choose to take part in this study, there is a risk that the intense chemotherapy treatment followed by limited surgery, may not be as good as the usual approach of chemotherapy plus radiation therapy followed by limited surgery, There is also a risk that you could have side effects from the intense chemotherapy treatment. Some of the most common side effects that the study doctors know about are:

- diarrhea, nausea, vomiting
- inflammation and sores occurring anywhere along the digestive tract but most common in the mouth which may cause difficulty swallowing, heartburn and abdominal pain
- tiredness
- rash

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. In Group 1 you will receive the intense chemotherapy treatment followed by limited surgery. In Group 2, you will receive the usual approach of chemotherapy plus radiation therapy followed by limited surgery.

In this study, you will also be asked to complete a few questionnaire(s) and diary at different times, to understand your Quality of Life and record the number of pills you take (if applicable).

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 CO.32 study is currently enrolling patients at cancer centres in Canada. For a full list of participating cancer centres please visit https://clinicaltrials.gov/study/NCT06205485