A gastroesophageal clinical trial

Adding a new monoclonal antibody medication to standard chemotherapy in HER2 Positive Advanced Gastroesophageal Adenocarcinoma

GA.4 | NCT06043427

What is the purpose of this study?

The purpose of this study is to find out what effects adding a new drug to the standard treatment has on you and your gastroesophageal cancer compared to the standard treatment given alone.

Why is this study important?

Targeted therapy is a type of treatment that uses drugs or other substances to identify and attack specific cancer cells. Some gastroesophageal cancer cells have high amounts of a receptor (protein) called human epidermal growth factor receptor 2 (HER2) which sends growth signals to cancer cells. Monoclonal antibody therapy is a type of targeted therapy used in the treatment of gastroesophageal cancer. It is not clear if adding a monoclonal antibody that targets and blocks the effect of HER2 to the usual treatment will work better than the usual treatment alone.

Who can participate in this study?

This trial is for:

- People with gastroesophageal cancer including cancers of the stomach, gastroesophageal junction or the esophagus
- People whose cancer cell tests showed high amounts of a receptor protein called HER2
- People who have already had or are currently receiving cancer treatment including a HER2 targeting agent with chemotherapy

This trial is not for:

- People who have had another type of cancer in the past 5 years. There are a few exceptions so speak with your doctor if this applies to you.
- People with a recent or uncontrolled heart condition such as congestive heart failure, heart attacks within the last 6 months or uncontrolled angina

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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 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:

- diarrhea
- infusion related reactions
- fatigue
- anemia

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

What can I expect?

If you choose to take part in this study, researchers will have to test a sample of your tissue to make sure the amount of a receptor (protein) called HER2 is present. If the test results are positive, you will then be randomly placed in one of two groups and you will receive other drugs commonly used to treat this disease either alone or with the new drug. In this study, you will also be asked to complete a questionnaire 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 GA.4 study is currently enrolling patients at cancer centres in Canada For a full list of participating cancer centres please visit https://clinicaltrials.gov/study/NCT06043427.

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