A brain cancer clinical trial

A clinical trial for brain tumours (gliomas) using screening for biomarkers, to target treatment approaches

CE9 | ACTRN: 12623000096651

What is the purpose of this study?

This trial is being done to answer the following question: Can survival be improved in your type of brain cancer by using personalized therapy based on changes in the DNA of your tumour? A pre-study screening will test a sample of your tumour tissue for biomarkers to see if you can participate in the study.

The purpose of this study is to compare the effects on you and your brain cancer with new and adapted drugs compared to commonly used drugs to treat this disease.

Why is this study important?

The drugs being studied are ones already being used as well as new drugs being developed for the treatment of brain cancer. Laboratory tests show that they may help slow the growth of brain cancer. The new drugs have been shown to shrink tumours in animals and have been studied in a few people and seem promising. It is not clear, however, if they can offer better results than standard treatments for individuals with brain cancer.

Who can participate in this study?

This trial is for:

- Adults aged 18 years and older
- Individuals with specific glioma brain cancers
- Individuals with evidence of progressing cancer
- Individuals who have had previous treatment with radiotherapy and chemotherapy

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 who have had previous cancer treatments with the drug bevacizumab
- Individuals who have had specific treatments given to participants during their final brain surgery before joining the study, such as using oncolytic viruses or Gliadel wafers
- Participants who have had serious continuing side effects from past cancer treatments

What are the risks?

If you choose to take part in this screening study and are eligible for a treatment sub-study, there is a risk that the study approach may not be as good as the usual approach for shrinking or stabilizing your cancer. The screening may also identify a biomarker, but there may not be a sub-study open for you to participate in, or you may not be eligible.

There may be some risks that the study doctors do not yet know about.

What can I expect?

If you decide to take part in the pre-study screening portion of this study, tumour samples will be tested to look for biomarkers that will help assign you to a sub-study. You will receive more information on the sub-study options once your biomarker profile is determined; this usually takes about 2-3 weeks.

The results of your screening will be reviewed by a panel of experts in cancer and cancer gene abnormalities, called the Molecular Tumour Advisory Panel, which will help determine if a sub-study drug might be a good option (match) for you. The specific sub-study offered will depend on a combination of your biomarker results, the sub-studies you are eligible for based on the requirements for each study, and which sub-studies are available when you are ready to start treatment.

If no biomarker changes were found that would assign you to an open sub-study and if you are eligible for more than one "biomarker negative" sub-studies which are open, you will be randomly assigned.

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 CE9 study is currently enrolling patients at cancer centres in Canada. For a full list of participating centres please visit: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=384830&isReview=true