

# A small cell lung cancer clinical trial

## MRI brain surveillance alone versus MRI surveillance and Prophylactic Cranial Irradiation (PCI): A randomized phase III trial in small-cell lung cancer (MAVERICK)

BRC.8 | NCT04155034

### What is the purpose of this study?

The purpose of this study is to compare the use of magnetic resonance imaging (MRI) surveillance combined with prophylactic cranial irradiation (PCI) to MRI surveillance alone in treating your lung cancer that can sometimes spread to the brain.

### Why is this study important?

MRI scans are used to monitor the possible spread of cancer with an MRI machine over time. PCI is radiation therapy that is delivered to the brain in hopes of preventing the spread of cancer into the brain.

Although PCI has been previously shown to lead to survival benefits, it is not clear if PCI is better than using radiation therapy only at the time when cancer is detected in the brain as long as the brain status is carefully monitored with MRIs. The use of PCI may also have side effects (described below). Therefore, the use of brain MRIs without PCI may reduce side effects, without affecting survival. In summary, this study will determine if monitoring with MRI scans alone (and delaying radiation therapy until the actual spread of the cancer) may be at least as effective for patients as the combination of PCI with MRI scans.

### Who can participate in this study?

This trial is for individuals who:

- Are adults 18 years of age or older with small cell lung cancer
- Have completed platinum-based chemotherapy with a positive response within the last 8 weeks
- Have no history of brain cancer, or evidence of cancer spread to their brain

This trial is not for individuals who:

- Have progressed following chemotherapy, or have other cancers currently requiring treatment
- Are not able to have an MRI (due to implanted metal device or other metal bodies)
- Have other ongoing illnesses
- Are pregnant or plan to become pregnant

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TO SEE IF THIS TRIAL IS A GOOD OPTION FOR YOU.

## What are the risks?

Although the use of MRI alone will reduce the side effects of PCI, if you choose to take part in this study, there is a risk that your cancer could progress in the brain because PCI was not used immediately. Some of the most common side effects of PCI that the study doctors know about are: hair loss, dry mouth, scalp reddening, tiredness, and memory loss. 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 usual approach of both PCI and having MRIs. In Group 2, you will not receive PCI, but will have MRIs alone.

In this study, you will also be asked to complete two questionnaires at different times to understand your Quality of Life.

## How can I find out more or join the study?

Always talk to your doctors and other health care providers if you are considering joining a clinical trial. You can share summaries like this with them and ask if they think joining the trial may be a good option for you.

The BRC.8 study is currently enrolling patients at centres in Canada. For a full list of participating centres please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and search using NCT04155034. (<https://clinicaltrials.gov/ct2/show/NCT04155034>).

Before you decide to join any clinical trial, you will be asked to review an *Informed Consent* document. Discussion with your physician and the informed consent document will tell you more about why the research is being done and your role as a participant. Please ask the study doctor if anything is not clear or if you have questions.

Joining clinical trials 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.

