A head and neck cancer clinical trial

Use of lymphatic mapping to guide radiotherapy to the neck in oropharyngeal cancer

HN11 | NCT05451004

What is the purpose of this study?

The purpose of this study is to compare the effects on you and your oropharyngeal cancer of radiotherapy to your neck guided by lymph node mapping (lymphatic mapping) using a special X-ray called Single Photon Emission Computed Tomography (SPECT-CT) compared to the current standard treatment where radiotherapy is given to both sides of the neck.

Why is this study important?

Radiotherapy guided by lymphatic mapping is a new approach being developed for the treatment of head and neck cancer. This approach has been studied in a few people and seems promising, but it is not clear if it can offer fewer side effects and better quality of life than the current standard treatment while still controlling the cancer.

Who can participate in this study?

This trial is for:

- Adults 18 years of age or older with oropharynx cancer who have not yet received any treatment
- Individuals with head and neck cancer on one side of the oropharynx only
- Individuals whose usual care involves radiotherapy to both sides of their neck
- Individuals who are able to undergo the lymphatic mapping procedure which includes injections around the tumour followed by a special X-ray called SPECT/CT

This trial is not for:

- Individuals who have had other types of head and neck cancers
- Individuals who have already had chemotherapy for their head and neck cancer
- Individuals with a history of heart or lung disease



What are the risks?

If you choose to take part in this study, there is a risk that the study approach may not be as good as the standard treatment for preventing your cancer from spreading or coming back.

There is also a risk that you could have side effects from the study approach which involves injection of a radioactive tracer (radiotracer) around the cancer. The radiotracer can cause allergic reactions during or after the injection.

Injecting the radiotracer around your cancer may cause side effects such as bleeding from either the injection site or from the cancer, swelling in the tissues at the back of your throat, pain from the injection, or difficulty breathing.

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 and you will receive either the new approach (radiation treatment with lymphatic mapping) or the radiation treatment that is commonly used to treat this disease.

In this study, you will also be asked to complete a few questionnaires 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. Discussion with your doctor 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 doctor if anything is not clear if you have questions.

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 HN.11 study is currently enrolling patients at cancer centres in Canada. For a full list of participating centres please visit www.clinicaltrials.gov and search using NCT05451004.

