# An esophageal cancer clinical trial

Looking at avoiding or delaying surgery for patients with squamous cell carcinoma of the esophagus ES.3 (NEEDS) | EudraCT 2020-000149-15

## What is the purpose of this study?

The purpose of this study is to find out if the approach of avoiding or delaying surgery in patients who have a good response to treatment with chemotherapy and radiation is as good as the usual approach for your esophageal cancer and provides better quality of life.

## Why is this study important?

This new approach could reduce the number of patients who need surgery for their esophageal cancer by limiting surgery to only those who are found to need it. Treatment without surgery might improve the quality of life for these patients.

# Who can participate in this study?

#### This trial is for:

- People 18 to 80 years old
- People with cancer of the esophagus that is confirmed to be a type called "squamous cell carcinoma"
- People whose tumour must be removable by surgery without requiring removal of the larynx

#### This trial is not for:

• People who have had other cancers within the last 5 years

#### What are the risks?

If you choose to take part in this study, there is a risk that the new approach of trying to avoid or delay surgery may not be as good as the standard approach of including surgery for all patients. There is also a risk that you could have side effects from the radiation or chemotherapy used on the trial. Some of the most common side effects that the study doctors know about are: diarrhea, nausea and vomiting, inflammation of sores within the digestive tract, swelling/redness at the injection site.. 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 get either the study approach in which you receive stronger chemotherapy and radiotherapy and esophagus surgery only if you need it, or the usual approach of receiving chemotherapy and radiotherapy followed by esophagus surgery.

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 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 **ES.3** study is currently enrolling patients at cancer centres in Canada. For further information please visit https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-000149-15/SE#summary

