

SEL-I-METRY Trial Summary

This trial is for people with thyroid cancer that has grown outside the thyroid (locally advanced) or spread to another part of the body (metastatic). It is for people with a type of thyroid cancer called differentiated thyroid cancer, which includes:

- papillary thyroid cancer
- follicular thyroid cancer
- hürthle cell thyroid cancer
- poorly differentiated thyroid cancer

More about this trial

Thyroid cancer is often treated with radioactive iodine (RAI). This uses a radioactive form of iodine called iodine 131 [Open a glossary item](#). The iodine 131 circulates in the body and is taken up by thyroid cancer cells. The radiation in the iodine then kills the cancer cells.

Thyroid cancer can sometimes stop taking up radioactive iodine. This is iodine refractory thyroid cancer. If this happens, it can be harder to treat thyroid cancer.

Selumetinib is a targeted cancer drug called a cancer growth blocker. It works by blocking certain proteins that tell cancer cells to divide and grow. Doctors think selumetinib can make refractory thyroid cancer cells sensitive to radioactive iodine again.

Everybody taking part in this trial has selumetinib followed by scans to find out how much iodine their thyroid is picking up.

If your thyroid starts picking up iodine again, then you might have radioactive iodine treatment (RAI).

The main aims of this trial are to:

- find out how well selumetinib and RAI work as a treatment
- learn about the side effects
- find out more about people's quality of life [Open a glossary item](#)

Who can enter?

The following bullet points list the entry conditions for this trial. Talk to your doctor or the trial team if you are unsure about any of these. They will be able to advise you.

You may be able to join this trial if all of the following apply:

- You have differentiated thyroid cancer that has grown outside the thyroid (locally advanced) or spread to another part of the body (metastatic cancer)
- Your thyroid cancer has stopped taking up radioactive iodine (iodine refractory)
- You have at least 1 area of cancer that can be seen and measured on a CT scan or MRI scan
- Your thyroid cancer got worse (progressed) in the past 12 months
- You have satisfactory blood tests results
- Your heart is working well
- You are well enough to carry out your normal activities, apart from heavy physical work (performance status of 0 or 1)
- You are at least 18 years old

Women must be willing to use reliable contraception during treatment and for 6 months afterwards if there is any possibility of becoming pregnant. Men must be willing to use reliable contraception during treatment and for 4 months afterwards if there is any possibility their partner could become pregnant.

You cannot join this trial if any of these apply:

Cancer related

- You have anaplastic thyroid cancer
- Your cancer has spread to your brain or spinal cord [Open a glossary item](#). You might still be able to take part if you have had treatment, you no longer have side effects and you haven't taken steroids for the past 4 weeks
- Doctors think that you are able to have treatments such as surgery or radiotherapy to cure your cancer
- You have moderate or severe side effects from previous anti cancer treatments apart from hair loss
- You have had selumetinib, sorafenib, lenvatinib or any other similar drugs
- You have had treatment with an anti cancer drug in the past month (6 weeks if it was mitomycin, suramin or a type of chemotherapy drug called nitrosourea [Open a glossary item](#))
- You have had another cancer in the last 5 years apart from successfully treated early cancers (carcinoma in situ [Open a glossary item](#)) of the bladder and cervix or successfully treated basal or squamous cell skin cancer

Medical conditions

- You have had a CT scan with a iodine contrast Open a glossary item in the past 2 months
- You have had a major operation or injury (trauma) in the past month
- You have had an experimental treatment in the past 4 weeks
- You are known to be sensitive to selumetinib, the thyroid stimulating hormone (TSH) or any other drug used in this trial
- You take drugs with a high amount of iodine such as amiodarone
- You have problems with your eyes such us glaucoma that isn't controlled or a condition called retinal epithelial detachment
- You have heart problems such as high blood pressure that is not controlled by medication, angina that is not controlled, heart failure that is causing symptoms, a heart attack in the past 6 months or problems with the valves (valvular heart disease)
- You have HIV
- You have hepatitis B or hepatitis C
- You have any other medical condition that the trial team thinks could affect you taking part in this trial

Other

- You are pregnant or breastfeeding

Trial Design

This is a phase 2 trial. The researchers need about 60 people to take part.

You have a thyroid scan called a radioactive iodine scan. This is to check where the cancer is and how much iodine the thyroid cells take up. Your doctor can tell you more about this.

Then you take selumetinib tablets. You take them twice a day, for up to 6 weeks.

28 days after starting selumetinib, you have more radioactive iodine scans. This is to see if there is a difference in the amount of iodine taken up by the thyroid cells.

If your thyroid cells take up the same amount of iodine, you have no more treatment as part of this trial. Your doctor will talk to you about what other treatments you can have. But if your thyroid cells take up more iodine, then you have radioactive iodine treatment (RAI).

Radioactive iodine treatment

You have 2 injections of a man made version of the thyroid stimulating hormone (recombinant human TSH). Then you take the radioactive iodine capsules and have scans. You need to stay in hospital and in isolation during treatment. This is the same as the standard treatment.

Quality of life

Everybody taking part in this trial completes a quality of life questionnaire before starting treatment and:

- a month after the end of selumetinib
- then every 3 months for a year

It asks about how you have been feeling and what side affects you have had.

Sample of tissue

The research team might ask you to have a sample of cancer taken (a biopsy [Open a glossary item](#)) before the start of treatment. Doctors want to look for certain substances that can tell why treatments work better for some people than others.

You do not have to agree to have the biopsy if you don't want to. You can still take part in this trial.

Hospital Visits

You see a doctor and have some tests before taking part. These tests might include:

- physical examination
- blood tests
- urine test
- a CT scan
- heart ultrasound (echocardiogram [Open a glossary item](#))
- heart trace (ECG [Open a glossary item](#))
- an eye test

During selumetinib treatment you see the trial doctor for blood tests and a physical examination every 2 weeks.

If you have RAI, you see the trial team:

- a month after the end of selumetinib
- every 3 months for a year
- then every 6 months

You also have a CT scan every 3 months. This continues for a year. Then you have a CT scan every 6 months.

If you don't have RAI you see the trial team a month after the end of selumetinib.

Side effects

The trial team monitor you during the time you have treatment and you have a phone number to call them if you are worried about anything. The team will tell you about all the possible side effects before you start the trial.

The most common side effects of selumetinib are:

- diarrhoea
- feeling or being sick
- skin rash
- tiredness (fatigue)
- a sore mouth and dry mouth
- a build up of fluid causing swelling of your hands and feet
- shortness of breath

Location

Recruitment Start: 28/03/2017

Recruitment end – 31/08/2018