ForPatients
by Roche

Cancer of Unknown Primary (CUP) Cancer

A Clinical Trial to Compare Targeted Therapy or Cancer Immunotherapy with Chemotherapy in Patients with Cancer of Unknown Primary (CUPISCO)

A Phase II Randomized Study Comparing the Efficacy and Safety of Targeted Therapy or Cancer Immunotherapy Versus Platinum-Based Chemotherapy in Patients With Cancer of Unknown Primary Site

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	33 Countries	NCT03498521 2017-003040-20 MX39795

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study will compare the efficacy and safety of molecularly-guided therapy versus standard platinum-containing chemotherapy in participants with poor-prognosis cancer of unknown primary site (CUP; non-specific subset) who have achieved disease control after 3 cycles of first-line platinum based induction chemotherapy.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT03498521 2017-003040-20 MX39795
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the CUPISCO clinical trial work? This clinical trial is recruiting people who have cancer called ‘cancer of unknown primary’ or CUP. Cancer of unknown primary is where the original location of the cancer (the primary site) is unknown.

How do I take part in this clinical trial? If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor.

If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests and procedures may be part of your regular medical care and may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again. You may also need to have a biopsy (a surgical procedure that involves taking a small tissue sample). This sample of your tumour will help your doctors to identify changes in your DNA (called ‘genetic mutations’) that may be causing your cancer to grow.

If there are mutations in the DNA of the cancer cells, a panel of doctors could use the information to help decide whether you should be treated with medicines called ‘targeted therapies’ or medicines called ‘immunotherapies’. Targeted therapies work by finding and attacking specific features of cancer cells, including DNA mutations. Immunotherapies work by helping the body’s immune system to destroy cancer cells. These targeted therapies will not be approved for your specific type of cancer, but are approved (or in development) for other types of cancer with the same type of genetic mutation.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial and what alternative treatments are available so that you may decide if you still want to take part. While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will be required either to not have heterosexual intercourse or to take contraceptive measures for safety reasons.

What treatment will I be given if I join this clinical trial? If you are able to take part in the clinical trial, you will first be given a chemotherapy drug into a vein (called an ‘intravenous infusion’) once every 3 weeks for 9 weeks (3 treatment cycles).

You will then have a scan to look at how your cancer is responding to the treatment. The next stage of your treatment will be based on the results of the scan. Your doctor will also look at what type of mutations your cancer cells have (also known as your ‘genomic profile’) to help find the most suitable treatment for you.

If the results of your scan show that your cancer has stayed the same size or decreased in size, you will be put into one of two groups randomly (like flipping a coin) where you will be given either 3 more treatment cycles of chemotherapy OR a targeted therapy or an immunotherapy. You cannot choose whether you stay on chemotherapy or receive targeted therapy or immunotherapy based on your personal genomic profile. You will have

a 3 in 4 chance of being given targeted therapy or immunotherapy and a 1 in 4 chance of being given 3 more cycles of chemotherapy. Neither you nor your trial doctor can choose the group you are in.

If the results of your scan show that your cancer has got bigger, you will be given targeted therapy or immunotherapy based on your personal genomic profile.

If you are receiving the targeted therapy or immunotherapy, you will be given the treatment for as long as it can help you and you do not have side effects. If you are receiving additional chemotherapy, your treatment will be stopped after receiving 3 treatment cycles, or earlier if you experience any side effects. You are free to stop this treatment at any time.

How often will I be seen in follow-up appointments, and for how long? After being given each stage of treatment, you will need to have blood and safety tests and meet your doctor every 3 weeks. Once you have completed your treatment, you will enter a follow-up period where you will need to visit your doctor for additional tests every 3 months. These visits are to see how your cancer is responding to the treatment and talk about any side effects that you may be having.

What happens if I'm unable to take part in this clinical trial? If your specific cancer type does not match what this clinical trial is looking at and/or the results of your blood tests are not in the range needed for the study, and/or if you have any other disease that would make your participation not safe, you will not be able to take part in this clinical trial. Your doctor will suggest other treatments for your cancer that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT03498521

Trial-identifier: NCT03498521