

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
Completed

Trial Runs In
33 Countries

Trial Identifier
NCT03498521 2017-003040-20
MX39795

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Randomized, Active-Controlled, Multi-Center Study Comparing the Efficacy and Safety of Targeted Therapy or Cancer Immunotherapy Guided by Genomic Profiling Versus Platinum-Based Chemotherapy in Patients With Cancer of Unknown Primary Site Who Have Received Three Cycles of Platinum Doublet Chemotherapy

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
All

Age
#18 Years

Healthy Volunteers
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.

ForPatients

by Roche

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

Inclusion Criteria:

- Histologically-confirmed unresectable cancer of unknown primary site (CUP) diagnosed according to criteria defined in the 2015 European Society for Medical Oncology (ESMO) Clinical Practice Guidelines for CUP
- No prior lines of systemic therapy for the treatment of CUP
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

- Candidate for platinum-based chemotherapy (according to the reference information for the intended chemotherapy)
- At least one measurable lesion according to Response Evaluation Criteria in Solid Tumors, version 1.1 (RECIST v1.1)
- Formalin-Fixed Paraffin-Embedded (FFPE) tumor tissue sample $\leq$ 4 months old that is expected to be sufficient for generation of a comprehensive genomic profile at a central reference pathology laboratory

Exclusion Criteria:

- Squamous cell CUP
- Participants who can be assigned to a specific subset of CUP for which a specific treatment is recommended by the 2015 ESMO Clinical Practice Guidelines for CUP or with a clinical and IHC profile indicative of a specific primary tumor (favorable prognosis CUP subsets): Poorly differentiated carcinoma with midline distribution; women with papillary adenocarcinoma of the peritoneal cavity; women with adenocarcinoma involving only the axillary lymph nodes; squamous cell carcinoma of the cervical lymph nodes; poorly differentiated neuroendocrine tumors; men with blastic bone metastases and elevated prostate-specific antigen (PSA); participants with a single, small, potentially resectable tumor; colon cancer-type CUP, including participants with a CK7 negative, CK20 positive, CDX-2 positive immunohistochemistry profile; CK7-positive, CK20-negative and TTF-1 positive tumors in a context suggestive of lung adenocarcinoma or thyroid cancer; IHC profile definitely indicative of breast cancer OR an IHC profile indicative of breast cancer and either a history of breast cancer or lymph nodes in the drainage areas of the breast; high-grade serious carcinoma histology and elevated CA125 tumor marker and/or a mass in the gynecological tract or any tumor mass or lymph node in the abdominal cavity; IHC profile suggestive of renal cell carcinoma and renal lesions, with a Bosniak classification higher than IIF; IHC profile compatible with cholangiocarcinoma or pancreatobiliary (or upper gastrointestinal carcinoma) AND 1 or 2 liver lesions without extrahepatic disease or with only pulmonary metastases and/or lymph nodes in the drainage areas of the liver
- Known presence of brain or spinal cord metastasis (including metastases that have been irradiated only)
- Histology and immunohistology profiles (per 2015 ESMO guidelines) that are not adenocarcinoma or poorly differentiated carcinoma/adenocarcinoma
- History or known presence of leptomeningeal disease
- Known human immunodeficiency virus (HIV) infection
- Significant cardiovascular disease
- Prior allogeneic stem cell or solid organ transplantation
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or for up to 7 months after the final dose of treatment