ForPatients
by Roche

Colorectal Cancer (CRC) Metastatic Colorectal Cancer

A study to look at how well different targeted therapies work to treat colorectal cancer that has spread to other parts of the body

A Study Evaluating the Safety and Efficacy of Targeted Therapies in Subpopulations of Patients With Metastatic Colorectal Cancer (Intrinsic)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	11 Countries	NCT04929223 2021-001207-33,2023-505163-37-00 WO42758

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 open-label, exploratory study is designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or combinations, in participants with metastatic colorectal cancer (mCRC) whose tumors are biomarker positive as per treatment arm-specific definition. Eligible participants with mCRC will be enrolled into specific treatment arms based on their biomarker assay results.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT04929223 2021-001207-33,2023-505163-37-00 WO42758
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is this study needed?

Colorectal cancer (CRC) is a type of cancer that starts in the colon or rectum. CRC that has spread to other parts of the body is called ‘metastatic CRC’, or ‘mCRC’.

Standard treatment for mCRC includes ‘targeted therapy’. Targeted therapy is a type of treatment that treats abnormal cells (e.g. cancer cells) in the body. It causes less harm to the normal cells. Doctors can look at the genes inside cancer cells for features that can be

targeted by therapy. But more types of targeted therapies are needed, and doctors need to understand how safe they are and how well they work on their own or in combination with other treatments.

This study is testing new targeted therapies. They are experimental medicines. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not yet approved the new targeted therapies for treating mCRC.

This study aims to test how well different targeted therapies work, how safe they are, and to understand what happens to them once in the body.

2. Who can take part in the study?

People of at least 18 years of age with mCRC that have certain genetic features can take part in the study. They must meet other criteria to join a particular treatment group, such as which treatments they have been given before, if any.

People may not be able to take part in this study if, for example, they have uncontrolled pain caused by their cancer, or cancer that has spread to the brain or spinal cord and causes symptoms. People who have certain medical conditions such as liver disease, or are taking certain treatments, are not able to take part. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

Participants will be screened to check if they are able to participate in the study. The screening period will take place from 1 month before the start of treatment.

Everyone who joins this study will be placed into a group (known as a ‘cohort’) that they fit the criteria for. The cohort will depend on the genetic features of the participant’s mCRC and may depend on the treatments they have received before.

The cohort will be given an experimental targeted therapy that matches their mCRC type. If more than 1 experimental targeted therapy or combination is available to a cohort, the cohort will be split into smaller groups and each group will be given a different study treatment. The chance of being given a certain study treatment will depend on the number of treatments available to a participant. This will be explained by the study doctor.

Targeted therapy will be given either on its own or in combination with other medicines. The medicines in this study may be given as pills (to be swallowed), injections under the skin, or drips into a vein (infusions) in treatment cycles. A treatment cycle is the period of treatment and recovery time before the next set of treatment is given – a cycle is usually 3 or 4 weeks.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants regularly. They will see how well the treatment is working and any unwanted effects participants may have. The number of visits the participants will have will depend on which cohort they are in. Participants who have cancer that gets worse or who have unmanageable and unwanted effects while they are being given a particular study treatment, may be able to be given a different treatment in this study if one is available and they meet the criteria.

Participants' total time in the study could be more than 2 years and will depend on how they tolerate treatment and how their cancer responds to treatment. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main result measured in the study to assess if the medicine has worked is how many people have a reduction of their cancer after treatment.

Other key results measured in the study include:

- How much time there is between the person's cancer first responding to treatment and the cancer getting worse
- The number of people whose tumours didn't grow or actually shrank after receiving treatment
- The number and seriousness of unwanted effects
- How the study treatments get to different parts of the body, and how the body changes and gets rid of it

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some other risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study medicines Participants may have unwanted effects of the medicines used in this study. These unwanted effects can be mild to severe, even

life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Participants will be told about the known unwanted effects of the study medicines and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known common unwanted effects include loose watery stools, throwing up, wanting to throw up, or a reaction to the injection or infusion.

The study treatments will be given as pills (to be swallowed), injections under the skin, or infusions. Known unwanted effects of injections under the skin include redness, swelling or rash on the skin where it has been pricked with a needle to give a treatment. Known unwanted effects of infusions include throwing up, wanting to throw up, a feeling of coldness that makes the body shiver, low or high blood pressure, fever, pain or discomfort in the head, frequent watery stools, shortness of breath, and cough.

The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.