ForPatients
by Roche

Melanoma

A clinical trial to look at how well treatment combinations work in people with melanoma (Morpheus-Melanoma)

A Study Evaluating the Efficacy and Safety of Multiple Treatment Combinations in Patients With Melanoma (Morpheus-Melanoma)

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT05116202 2022-502939-19-00 BO43328

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 evaluate the efficacy, safety, and pharmacokinetics of treatment combinations in cancer immunotherapy (CIT)-naive participants with resectable Stage III melanoma (Cohort 1) and in participants with Stage IV melanoma (Cohort 2). The study is designed with the flexibility to open new treatment arms as new treatments become available, close existing treatment arms that demonstrate minimal clinical activity or unacceptable toxicity, and modify the participant population.

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT05116202 2022-502939-19-00 BO43328
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the Morpheus-Melanoma clinical trial needed?

Melanoma is a type of skin cancer that can be difficult to treat if it spreads to other organs in the body (known as ‘advanced’ melanoma). Cancer immunotherapies, such as nivolumab and ipilimumab, use the body’s immune system to destroy cancerous cells and have shown encouraging results treating advanced melanoma and melanoma that has spread to only nearby lymph nodes and can be removed with surgery (known as ‘localised resectable’ melanoma).

In this trial, different types of immunotherapy drugs (RO7247669, tiragolumab and atezolizumab) are being tested to see if new combinations of treatments will provide better health outcomes for people with localised or advanced melanoma. RO7247669, tiragolumab and atezolizumab are experimental drugs, which means health authorities have not approved them for treating melanoma.

2. How does the Morpheus-Melanoma clinical trial work?

This clinical trial is recruiting people with melanoma. Everyone who joins this clinical trial will be enrolled in one of two groups, depending on the stage of their disease. People can join Group 1 if they have localised resectable melanoma, or Group 2 if they have advanced melanoma. People who take part in this clinical trial (participants) will be given the clinical trial treatment shown in Section 5. Participants in Group 1 will receive two rounds of treatment over 6 weeks (unless they have unacceptable side effects) and undergo surgery in Week 7. The clinical trial doctor will see them on weeks 1 and 4 for treatment, weeks 6, 7, and 10 (pre-surgery, surgery and post-surgery), and Week 13 (treatment completion). A follow-up visit (in the hospital) will occur after 6 months, with further follow-up checks every 3 months after that (which can be completed remotely/by phone). Participants in Group 2 will be given treatment for as long as it can help them unless they have unacceptable side effects. The clinical trial doctor will see them every 3 weeks until treatment is stopped, then will complete follow-up checks every 3 months after that (which can be done remotely/by phone). Hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. Total time of participation in the clinical trial will vary, depending on which group they are in, how well their cancer responds to treatment and whether they stop treatment because of side effects. This could range from 1 day to about 4 months plus follow-up time for participants in Group 1 or for up to 5 years plus follow-up time for participants in Group 2. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the Morpheus-Melanoma clinical trial?

The main clinical trial endpoint (the main result that is measured in the trial to see if the medicine has worked) for Group 1 is the number of participants whose cancer is smaller or is not detectable after treatment in tissue samples removed during surgery (pathologic response rate).

The main clinical trial endpoint for Group 2 is the number of participants with a smaller tumour after treatment that remains at a reduced size at least 4 weeks later (objective response rate).

The other clinical trial endpoints include:

- The amount of time between the start of treatment and cancer getting worse, and between surgery and cancer coming back (Group 1)

- The number of participants whose cancer got smaller before surgery (Group 1)
- How long participants live and without their cancer worsening (Group 2)
- The amount of time between cancer getting better and then getting worse (Group 2)
- The number of participants with controlled cancer (none detectable, smaller tumours or tumours that stay the same size) for at least 3 months (Group 2)
- How long participants live, and the number and seriousness of any side effects (Groups 1 and 2)

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old and have been diagnosed with either localised resectable melanoma or advanced melanoma, which has worsened during or after a maximum of two previous lines of treatment. People may not be able to take part in this trial if they have certain other medical conditions, have previously received certain treatments, are/planning to become pregnant, or are breastfeeding. Participants may be unable to join Group 1 if they have received previous immunotherapy treatment. Participants may be unable to join Group 2 if they have cancer that has spread to the brain or spinal cord and causes symptoms.

5. What treatment will participants be given in this clinical trial?

Group 1 will be split into six groups randomly (by chance) and given, as an infusion into a vein once every 3 weeks, either 1) nivolumab plus ipilimumab, 2) high dose RO7247669, 3) high dose RO7247669 plus tiragolumab, 4) low dose RO7247669, 5) low dose RO7247669 plus tiragolumab, or 6) atezolizumab plus tiragolumab. Two rounds of treatment will be given over 6 weeks and all participants will undergo surgery in Week 7.

Everyone in Group 2 will be given high dose RO7247669 plus tiragolumab, as an infusion once every 3 weeks. This is an open-label trial, which means everyone involved, including the participant and the clinical trial doctor, will know the clinical trial treatment the participant has been given.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly. Potential participants will be told about the known side effects of nivolumab, ipilimumab, atezolizumab, tiragolumab and RO7247669 and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. All of these drugs will be given as an intravenous (into a vein) infusion. Participants will be told about any known side effects of intravenous infusions.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.