

Advanced Liver Cancers Hepatocellular Carcinoma (HCC)

A clinical trial to look at how safe and effective different combinations of immunotherapy-based treatments are at reducing tumour size in people with advanced liver cancers

A Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Advanced Liver Cancers (Morpheus-Liver)

Trial Status
Recruiting

Trial Runs In
7 Countries

Trial Identifier
NCT04524871 2020-001743-10
GO42216

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 is a Phase Ib/II, open-label, multicenter, randomized umbrella study in participants with advanced liver cancers. 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, modify the participant population, or introduce additional cohorts of participants with other types of advanced primary liver cancer. Cohort 1 will enroll participants with locally advanced or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy for their disease. Eligible participants will initially be randomly assigned to one of several treatment arms (Stage 1). Participants who experience loss of clinical benefit or unacceptable toxicity during Stage 1 may be eligible to receive treatment with a different treatment combination (Stage 2). When a Stage 2 treatment combination is available, this will be introduced by amending the protocol.

Hoffmann-La Roche
Sponsor

Phase 1/Phase 2
Phase

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Eligibility Criteria:

Gender
All

Age
≥18 Years

Healthy Volunteers
No

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1. Why is the MORPHEUS-liver clinical trial needed?

Hepatocellular carcinoma (HCC) is the most common type of liver cancer. Most people are first diagnosed with HCC once it has spread to surrounding tissues or lymph nodes (known as 'advanced HCC') or to other parts of the body (known as 'metastatic HCC').

The standard first treatment for HCC that cannot be removed with surgery (known as 'unresectable' HCC) is cancer immunotherapy ('CIT', such as atezolizumab plus bevacizumab), which helps the body's immune system to destroy cancer cells. The anti-cancer activity of CITs may be boosted when different treatments are given at the same time – as CIT combinations. New CIT combinations are needed to improve health outcomes for people with advanced HCC.

This clinical trial aims to compare the effects, good or bad, of different combinations of CIT in people with locally advanced or metastatic HCC. As the trial progresses, the safety and effectiveness of other new treatment combinations may be tested.

2. How does the MORPHEUS-liver clinical trial work?

This clinical trial is recruiting people with HCC. People can take part if they have advanced, metastatic or inoperable HCC. People who take part in this clinical trial (participants) will be given one of several CIT combinations (consisting of at least one CIT drug) for as long as it can help them. If participants have unacceptable side effects to the CIT combination, or their disease gets worse, they may be given a different CIT combination if one is available, and if they agree to it. The clinical trial doctor will see participants regularly. These hospital visits will include checks, such as a tumour assessment scan, to see how the participant responds to treatment and any side effects they may have. The tumour assessment scans will occur every 6 weeks for the first 48 weeks of the trial and then every 6 or 12 weeks after that. After the final dose of treatment, the clinical trial doctor will follow-up with participants about every 3 months for as long as they agree to it. Participants' total time in the clinical trial will depend on how they tolerate treatment and how their cancer responds to treatment, which could be up to more than 1 year. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the MORPHEUS-liver clinical trial?

The main clinical trial endpoint (the main result measured in the trial to see if the treatment combinations have worked) is the number of participants with either cancer that has reduced in size or no detectable cancer (known as the 'objective response rate').

The other clinical trial endpoints include:

- The length of time between the start of treatment and cancer getting worse (known as 'progression free survival')

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- How long participants live (known as 'overall survival')
- The amount of time between cancer getting better from treatment and then getting worse (known as 'duration of response')
- How many participants have tumours that stay the same or reduce in size for at least 3 months (known as 'disease control rate')

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 advanced, metastatic or unresectable HCC and have not been treated for it with drugs that affect the whole body (known as 'systemic' treatment). People who have had treatments that are given to the tumour directly, such as surgery or radiotherapy, are allowed to take part.

People may not be able to take part in this trial if they have HCC that has spread to the brain or spinal cord and causes symptoms, rare types of HCC (such as fibrolamellar HCC and sarcomatoid HCC) or have certain other medical conditions such as infections, autoimmune, heart or lung disease. People who have previously been given certain treatments, including CITs, or who are pregnant or breastfeeding or are intending to become pregnant during the clinical trial, are not able to take part. There are other specific criteria that participants may need to meet to be given a particular CIT treatment combination in this clinical trial.

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

Participants will be given a combination of CITs. The combinations may include atezolizumab plus bevacizumab with or without: tiragolumab, tocilizumab, TPST-1120 or ADG126, or may be a combination of RO7247669 plus bevacizumab. Treatment combinations will be given by mouth (orally) or as an infusion into a vein every 3 or 4 weeks depending on the CIT combination.

Participants will be placed in a CIT combination treatment group randomly (by chance) depending on the safety criteria they meet and the number of groups available. Participants may also receive treatment with tocilizumab as an infusion into the vein, if they experience certain side effects (called 'cytokine release syndrome') during the clinical trial.

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

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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

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be told about the known side effects of CITs and possible side effects based on human and laboratory studies or knowledge of similar drugs. CITs will be given by mouth (orally) or as an infusion into a vein (intravenous infusion). Participants will be told about known side effects of intravenous infusion and will be closely monitored during the clinical trial; safety assessments will be performed regularly.

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.