ForPatients
by Roche

Cancer

A clinical trial to see if a digital health solution, such as a digital patient monitoring solution, can help improve health outcomes in people who are being given anti-cancer treatment

Clinical Impact and Utility of Digital Health Solutions in Participants Receiving Systemic Treatment in Clinical Practice

Trial Status	Trial Runs In	Trial Identifier
Terminated	5 Countries	NCT05694013 2023-504342-55-00 MO42720

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:

Interventional platform study investigating the impact of digital health solutions on health outcomes and health-care resource utilization in participants receiving systemic treatment in clinical practice (ORIGAMA)

Trial Summary:

This study will evaluate the clinical impact and utility of digital health solutions (DHS) on health outcomes and health-care resource utilization in people receiving systemic anti-cancer treatment (approved or non-approved) in clinical practice.

Hoffmann-La Roche Sponsor	**Phase 2/Phase 3** Phase

NCT05694013 2023-504342-55-00 MO42720
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

1. Why is the ORIGAMA (Cohort A) clinical trial needed?

Digital monitoring of a person's disease- or treatment-related symptoms and health during treatment may improve treatment results, reduce the number of serious side effects and

help doctors and patients to manage symptoms more effectively. The Digital Patient Monitoring (DPM) solution is a web- and app-based electronic system that allows people with cancer to provide information on how they are coping with disease and treatment to their clinics' care team in a structured and regular way. This clinical trial aims to assess how well the DPM system works to improve health outcomes in people receiving anti-cancer treatment and reduce the use of healthcare resources.

2. How does the ORIGAMA (Cohort A) clinical trial work?

This clinical trial is recruiting people who are being given anti-cancer treatment. The people who take part in the trial are known as 'participants'. The trial will test the DPM system in participants with different types of cancers or who are receiving different types of treatments.

People can take part if they have either lung cancer (non-small cell lung carcinoma [NSCLC] that has spread in the body, or extensive-stage small-cell lung carcinoma), or liver cancer (hepatocellular carcinoma) that has grown or spread in the body or cannot be removed with surgery.

Throughout the trial, half of the participants will be asked to complete weekly questionnaires on disease- or treatment-related symptoms they have using the DPM system, via an app installed on their internet-capable device (computer or mobile phone) or via a web browser. Participants who are not selected to use the DPM system will be able to report symptoms according to normal practice in their local area. All participants will be given access to a second online or paper-based form, to report on their health-related quality of life and impact of symptoms on daily life every 6 weeks.

Participants will be given a health authority-approved anti-cancer treatment containing atezolizumab according to normal practices in the area where they live.

The clinical trial doctor will see them regularly to check how the participant responds to the treatment and any side effects they may have. The total time in the clinical trial will be up to about 1 and a half years depending on the type of cancer and treatment being given. Participants will be seen at a follow-up visit about 1 month after their last dose and contacted by telephone after 3 months to check on their health. Participants can stop trial treatment and/or stop using the DPM system and leave the clinical trial at any time.

3. What are the main endpoints of the ORIGAMA (Cohort A) clinical trial?

The main clinical trial endpoint (the main result measured in the trial) is how much participants' symptoms interfere with daily life at 3 months after the start of the trial.

Other clinical trial endpoints include the:

- Number and length of emergency or unscheduled visits/stays to hospital due to symptoms or side effects
- Number and seriousness of side effects
- Number of people who pause, change the dose of, or stop treatment due to side effects
- Change in quality of life and how symptoms affect daily life throughout the trial

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 an email address, access to an internet-capable device (smartphone, tablet or PC) and access to an internet connection. People may not be able to take part in this trial if they have a physical or mental condition that prevents them from using the apps provided, are receiving treatment from another clinical trial or certain treatments or certain medical conditions such as long-term infections. Women who are pregnant or breastfeeding or are planning to become pregnant during or shortly after the trial will not be able to take part.

5. What treatment will participants be given in the ORIGAMA (Cohort A) clinical trial?

Everyone will be given anti-cancer treatment and support from their care team with or without the use of the DPM system. Participants will have an equal chance of being given or not being given the DPM system to use.

6. Are there any risks or benefits in taking part in the ORIGAMA (Cohort A) clinical trial?

The safety or effectiveness of the experimental DPM system 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 or device (the DPM system)

Participants may have side effects (an unwanted effect) from the drugs or DPM system used 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. The possible side effects of a particular treatment are the same for people who join the trial and for people who are treated with the same medicine separately from the trial.

Participants will be told about any known risks of the DPM system or side effects of anti-cancer treatments containing atezolizumab, the methods for providing the treatments and where relevant, potential risks or side effects based on human and laboratory studies or knowledge of similar drugs, devices and procedures. No risks are currently known to be associated with the DPM system.

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.

For more information about this clinical trial see the For Expert tab on the specific ForPatients page or follow this link to ClinicalTrials.gov

Inclusion Criteria:

Inclusion Criteria: All Participants

- Email address, access to an internet-capable device (smartphone, tablet, or PC), and access to an internet connection

Inclusion Criteria: Cohort A

- Histologically confirmed diagnosis for mNSCLC, ES-SCLC, or HCC (Child Pugh A)
- Systemic therapy naive
- Prescribed an atezolizumab IV regimen
- Easter Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2

Inclusion Criteria: Cohort B

- Complete resection of a histologically or cytologically confirmed Stage IIB-IIIB (T3-N2) NSCLC
- PD-L1 positive
- Have completed adjuvant chemotherapy at least 4 weeks and up to 12 weeks prior to randomization and must be adequately recovered from chemotherapy treatment
- ECOG Performance Status of 0 or 1
- Adequate hematologic and end-organ function
- For participants receiving therapeutic anticoagulation: stable anticoagulant regimen
- Negative for hepatitis B virus (HBV) or hepatitis C virus (HCV)

Exclusion Criteria:

Exclusion Criteria: All Participants

- Any physical or cognitive condition that would prevent the participant from using the DHS
- Participants not proficient with any of the available DHS language translations or with psychiatric/ neurologic disorders or any condition that may impact the participant's ability to use the DPM solution
- Currently participating in another interventional trial

- History of malignancy within 5 years prior to initiation of study treatment, with the exception of the cancer under investigation in this study and malignancies with a negligible risk of metastasis or death

Exclusion Criteria: Cohort A

- Concomitant anti-cancer therapy at the time of starting atezolizumab (IV) regimen on the index date which is not part of a locally approved combination therapy with atezolizumab
- Participants not receiving atezolizumab, but an atezolizumab biosimilar or non-comparable biologic
- Participants currently using another DPM or ePRO solution for symptom management and/or reporting

Exclusion Criteria: Cohort B

- Participants known to have a sensitizing mutation in the EGFR gene or an ALK fusion oncogene
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently)
- History of leptomeningeal disease
- Uncontrolled or symptomatic hypercalcemia
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Active tuberculosis
- Significant cardiovascular disease
- Major surgical procedure, other than for diagnosis, within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- Severe infection within 4 weeks prior to initiation of study treatment, including, but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia, or any active infection that could impact participant safety
- Treatment with therapeutic oral or IV antibiotics within 2 weeks prior to initiation of study treatment
- Prior allogeneic stem cell or solid organ transplantation
- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment, or anticipation of need for such a vaccine during atezolizumab treatment or within 5 months after the final dose of atezolizumab
- Current treatment with anti-viral therapy for HBV
- Treatment with investigational therapy within 28 days prior to initiation of study treatment
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies
- Treatment with systemic immunostimulatory agents (including, but not limited to, interferon and IL-2) within 4 weeks or 5 drug elimination half-lives (whichever is longer) prior to initiation of study treatment
- Treatment with systemic immunosuppressive medication (including, but not limited to, corticosteroids, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor-# [TNF-#] agents) within 2 weeks prior to initiation of study treatment, or anticipation of need for systemic immunosuppressive medication during study treatment
- History of severe allergic anaphylactic reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity to Chinese hamster ovary cell products or to any component of the atezolizumab formulation
- Pregnancy or breastfeeding
- Known allergy or hypersensitivity to hyaluronidase, bee or vespid venom, or any other ingredient in the formulation of rHuPH20
- Pathology (e.g., lower extremity edema, cellulitis, lymphatic disorder or prior surgery, preexisting pain syndrome, previous lymph node dissection, etc.) that could interfere with any protocol-specified outcome assessment

- Spinal cord compression not definitively treated with surgery and/or radiation, or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for # 2 weeks prior to randomization
- Participants currently using another DPM or ePRO solution for symptom management and/or reporting