**PATIENT INFORMATION SHEET**

**Randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy on respiratory efficacy on respiratory symptomatology of montelukast in patients with persistent**

**Study code:** PROYECTO E-SPERANZA COVID

**Sponsor:** Institute for Primary Care Research Jordi Gol (IDIAPJGol)

**Principal Investigator:** Francisco Mera Cordero

**Center:** Direcció Atenció Primària Costa de Ponent, Institut Català de la Salut.

**E-mail:** fmera@ambitcp.catsalut.net

We would like to invite you to participate in a research study. Before deciding whether you wish to participate or not, it is necessary to understand what the study consists of and what it means to you.

Below you will find information about the study. Please take the time to read the following information carefully and ask us any questions you may have or if you would like more information.

If you have any questions you may have or would like more information. In addition, you may consult with whomever you feel appropriate.

The study has been approved by the Ethical Committee for Research in Medicines of the Jordi Gol Primary Care Research Institute and by the Spanish Agency for

Medicines and Health Products, in accordance with the legislation in force, Royal Decree 1090/2015, of December 4, and the European Regulation 536/2014, of April 16, regulating clinical trials with medicinal products. regulating clinical trials with medicinal products.

This is a study that aims to assess whether Montelukast compared to placebo improves respiratory symptoms and quality of life in patients who, after acute COVID-19 infection, show persistent COVID-19 infection, have persistence of symptoms beyond four weeks.

**Voluntary participation**

We are inviting you to participate in the study because you have been diagnosed with COVID, and you have persistent respiratory symptoms (more than 4 weeks since onset).

Participation is voluntary. It is up to you whether or not you wish to participate, without having to to justify yourself. The treatment of your current illness and your future health problems will not be affected by your decision to participate.

Your decision whether or not to participate in the trial will be up to you.

If you wish to participate, your doctor will explain the study to you and give you a copy of this information sheet, which you may keep.

If you decide to participate, you will be asked to fill out and sign an informed consent form. You should keep a copy of the informed consent form.

In addition, even if you have agreed to participate in the study, you may decide to withdraw at any time, without giving any reason.

Your decision to stop participating will not affect the quality of care you receive now. the quality of care you receive now and in the future. If you decide to leave the research, no more data or samples will be collected for the research, but we will use the information collected up to that point, unless you tell us otherwis**e.**

**Patient Information and Informed Consent Sheet**

**Version 1.4, 28-07-2021**

**Aim of the study**

Some patients who have had COVID-19 disease continue with some symptomatology beyond 4 weeks after the onset of symptoms, which is called persistent COVID. One of the most common symptoms of persistent COVID is shortness of breath, called dyspnea.

The aim of the study is to determine the efficacy of montelukast in improving respiratory symptoms and associated quality of life in patients with symptoms more than 4 weeks after onset of the disease.

**Description of the study**

You are being invited to participate in this study because you are experiencing persistent respiratory symptoms persistent respiratory symptoms 4 weeks after disease onset COVID-19.

You would not be able to participate in this study if you were a minor, over 80 years of age, had been hospitalized for COVID-19, were hospitalized for COVID-19, had a chronic respiratory disease, were lactose intolerant, were pregnant or lactose intolerant, were pregnant, or were breastfeeding.

This study will involve 284 patients and will be conducted in 10-15 primary care centers in Catalonia. There are 2 treatment groups, montelukast or placebo. The placebo is a capsule with the same appearance as the drug to be studied, montelukast, but which does not contain any pharmacologically active substance and therefore is not expected to have any effect. Assignment to treatment is randomized and neither you, nor the practitioner giving you the medication, will know which one you are taking.

Montelukast is a marketed drug with a known safety profile, indicated for the treatment of mild to moderate persistent asthma that is with other adequately controlled with other treatments or in exercise-induced asthma.

As it is a drug approved by the competent health authorities, there is information available for everyone to access on the information on the side effects of montelukast is available to everyone.

The most frequently reported adverse effects have been headache and abdominal pain, upper respiratory infections, headache and abdominal pain, upper respiratory infections respiratory infections, diarrhea, nausea, elevated transaminases, fever and skin rash.

Rarely, cases of angioedema, increased possibility of hemorrhage have been described, hepatitis, vasculitis and neuropsychiatric alterations (hallucinations, disorientation, suicidal thinking).

Please talk to your doctor if you experience any undesirable effects during the study.

**Possible benefits**

You may not get any health benefits from participating in this study. However, the results of the study will allow us to gain information about the effectiveness of the treatment that may benefit future patients.

You will not receive any financial compensation for your participation in the study.

Information and consent for the processing of personal data in research projects pharmacologically active substance and is therefore not expected to have any effect. Assignment to treatment is randomized and neither you nor the professional providing the medication will know which of the two treatments you will receive. You have the same chance of receiving montelukast as placebo (50%).

**Study visits**

Participation in the study will last a total of 8 weeks. During the first 4 weeks you will need to take the treatment as explained by your doctor and make the weekly visits explained below. After completion of the treatment, you will receive another phone call after 4 weeks to check your health status.

**Study visits**

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In total, 6 visits will be made, 3 in person (days 1, 14 and 28) and 3 by telephone (days 7, 21 and 56).

Participating in the study means being interviewed by a primary care physician or nurse at a health center or home, by telephone or in person, and taking the assigned treatment or placebo, once a day in the evening, for 4 weeks. You will also be asked for a baseline blood test, a 1-minute exercise test, which may cause some fatigue or choking, and to answer questionnaires related to your disease.

**Below is a summary of the study visits:**

 Visits

Procedures

Initial Visit

Signing of informed consent

Blood test.

Questions about your health status and COVID-19 disease.

Usual physical examination.

Questionnaires to know your symptomatology and quality of life.

Sit-to-stand exercise test, which consists of sitting down and getting up from a chair without resting the hands as many times as possible for 1 minute.

Random assignment to treatment and delivery of study medication.

Telephone calls on days 7, 21 and 56.

Questions about their health status and visits to health centers.

Questionnaires to know their symptomatology and quality of life.

Questions about taking the study medication (except for the call on day 56).

Face-to-face visits on days 14 and 28

Questions about health status and visits to health centers.

Questionnaires to know your symptomatology and quality of life.

Sit-to-stand exercise test.

Questions about taking the study medication. In addition, at the visit on day 28, you will be asked to return the bottle of medication given to you at the initial visit.

**Potential Risks**

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Rarely, angioedema, increased possibility of bleeding, hepatitis, vasculitis and neuropsychiatric disturbances (hallucinations, disorientation, suicidal thinking) have been reported.

Please talk to your doctor if you experience any undesirable effects during the study.

**Possible benefits**

You may not get any health benefits from participating in this study. However, the results of the study will allow us to obtain information about the effectiveness of the treatment that may benefit future patients.

You will not receive any financial compensation for your participation in the study.

Information and consent for the processing of personal data in research projects

The processing of this data will be carried out in compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR), and the Organic Law 3/2018, on Data Protection and guarantee of digital rights, and therefore we inform you that you may exercise your rights of access, rectification, deletion, opposition, limitation of processing and data portability (LOPD-GDD), through the principal investigator of the project as Data Controller. You can contact the Data Protection Delegate through dpd@ticsalutsocial.cat.

By signing this document you expressly consent to your data being processed for research purposes within the framework of this Project, in accordance with article **6.1.a, 9.2.a of the RGPD. These data will be kept for the time necessary to carry out the project.**

We inform you of your right to withdraw your consent to the processing of this data at any time by email (fmera@ambitcp.catsalut.net), as well as your right to file a complaint with the Catalan Data Protection Authority against any action of the Data Controller that you consider violates your rights.

No communications of your data to third parties beyond those provided for by law, or international transfers are foreseen.

Thank you for taking the time to read this fact sheet and for considering your participation in the study.

The results of the study will be published in scientific journals, without any personal identification.

If you wish to know in more detail the results or the treatment you received during the study, you can contact the research team.

If during the participation in the study you have any questions or need more information you can contact:

Francisco Mera Cordero

Direcció Atenció Primària Costa de Ponent, Institut Català de la Salut

email. fmera@ambitcp.catsalut.net

**Randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy on respiratory efficacy on respiratory symptomatology of montelukast in patients with persistent**

**Study code:** COVID E-SPERANZA PROJECT

**Principal Investigator:** Francisco Mera Cordero

**Direction of Primary Care Costa de Ponent, Institut Català de la Salut. e-mail:**

fmera@ambitcp.catsalut.net

PATIENT CODE: .............................

I,......................................................................................................................(patient's name)

I have read the information sheet given to me about the study.

- I have been able to ask questions about the study.

- I have received enough information about the study.

- I have spoken to .............................................................................(name of investigator).

- I understand that my participation is voluntary.

- I understand that I can withdraw from the study:

- Whenever I want.

- Without having to explain myself.

- Without any repercussions on my medical care.

In accordance with the provisions of the Organic Law 3/2018, of December 5, 2018, on the protection of personal data and guarantee of digital rights, I declare that I can withdraw from the study of personal data and guarantee of digital rights, I declare that I have been informed of my rights, the purpose of the of my rights, of the purpose of the collection of my data and of the recipients of my information.

I will receive a signed and dated copy of this informed consent document.

I freely give my consent to participate in the study.

Signature of the patient Patient's signature Investigator's signature

Date: / / Date: / **/**