Informed Consent Form

Search title: "Corticosteroid treatment for Post-COVID-19 persistent interstitial lung disease".
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You are invited to participate, as a volunteer, in a research study. If you agree, after being informed about all information, sign at the end of this document. If you do not agree to participate in the research, you will not be harmed in any way and your service will not be different from what it has been like up until now.

Lung infection with the new coronavirus can lead to persistent lung disease. This study intends to verify the effectiveness of corticosteroid treatment in people who maintain lung changes 3 months after coronavirus infection.

Initially, you are invited to carry out two tests to assess how your lungs are doing after coronavirus pneumonia (tests for inclusion in the study):

- Spirometry with carbon monoxide diffusion capacity: this test will evaluate the function of your lungs, in which you will be asked to blow with your maximum force and continue blowing until all your lungs are emptied. Afterwards, you will quickly fill your chest with air. This exam can cause discomfort, stimulate coughing, cause dizziness, a feeling of tightness in the chest and even fainting in very rare cases. If you have any of these complaints, a doctor will be by your side to evaluate and care for you.

- High-resolution chest tomography. This exam will be carried out in the radiology department, where you will be asked to lie down on a bed where you will enter a small tunnel for a few seconds. The risks of this exam are related to exposure to radiation and the use of iodinated contrast. The consequences of exposure to radiation are very rare and occur when many radiological examinations such as CT scans are carried out, which can increase the risk of cancer in general.

After identifying whether you still have lung changes due to the coronavirus infection through these two tests, you will be invited and, if you agree to participate, you will undergo the tests described below and begin a treatment that we will explain below:

- Six-Minute Walk Test: In this test, you will walk as fast as possible on a walking track for 6 minutes. Your heart rate, respiratory rate, blood pressure and blood oxygen concentration will be measured using an oximeter at the beginning, in the middle and after the end of the test. This test can cause discomfort, fatigue, dizziness and there is a risk of falling due to the effort. If you have any symptoms during the test, you will be evaluated by a doctor immediately.
- Electrocardiogram. You will undergo this test to detect possible heart conditions that can cause shortness of breath and confuse symptoms related to residual lung lesions caused by the coronavirus.
- SF-36 quality of life questionnaire: questionnaire to find out about your ability to perform daily activities, whether you have pain, how your general health is, your

emotional state and your mental health. This questionnaire will be administered by the researcher and all the questions will be explained in a way that you can answer without difficulty and will take about 10 minutes to complete.

- Two other questionnaires will be administered: one about how short of breath you feel called the Medical Research Council (MRC) and another questionnaire about your ability to carry out your daily activities, called the Post-COVID-19 Functional Status Scale (PCFS). All the questions will be explained in a way that you can answer without difficulty, and it will take about 5 minutes to complete both questionnaires.
- Two other questionnaires will be administered: one about the degree of shortness of breath you feel, called the Medical Research Council (MRC) questionnaire, and another about your ability to carry out your daily activities, called the Post-COVID-19 Functional Status Scale (PCFS). All questions will be explained in a way that you can answer without difficulty, and it will take about 5 minutes to answer both questionnaires.

After this assessment, if you agree to participate in the study, you will receive a treatment within two alternatives: either you will be part of a group that will receive prednisolone or you will be part of a group that will receive a placebo. Half of the people included will use prednisolone and the other half will use a placebo. The decision of who will take one or the other will be random and made by computer. Neither you nor your doctor will know which of the two pills you will use and will also not be able to choose your treatment. Prednisolone is a corticosteroid, a medication that has anti-inflammatory action and we hypothesized that it can reduce inflammation in your lungs and improve these persistent lesions. The placebo is a pill that does not contain the medication. We need to conduct the study this way because we need to know whether the pill really has an effect on persistent lung changes or whether time alone is enough to improve lung lesions.

If at the end of the follow-up we find that the treatment with prednisolone really has an effect on lung changes and is superior to the treatment with placebo, and you were part of the group that used the placebo, you will subsequently receive treatment with prednisolone (corticosteroid).

The use of oral corticosteroids for a prolonged period of time may cause an increase in blood pressure, an increase in blood sugar even in non-diabetic people, bone weakness (osteoporosis), an increase in pressure inside the eye, spots on the skin, permanent marks on the skin (stretch marks) and other changes in the body. However, a short period of use of one month with slow withdrawal over approximately 4 weeks brings a lower probability of these adverse effects and they are transient effects that occur during the period of use and improve after discontinuation, such as increased blood pressure levels and increased blood sugar levels.

After the first assessment, we will monitor you for 6 months. In total, you will visit the hospital on 3 occasions. During these visits, you will undergo all the tests mentioned above. Between these visits, we will contact you by telephone on a monthly basis to check how you are doing and whether you have had any side effects from the treatment. If you have any side effects, the doctor who is making the telephone contact will schedule an additional assessment.

The information you provide during the interviews and your medical record data will be kept absolutely confidential to prevent your information from being known by other people. You will be identified not by your name but by the acronym of the first letters of your name in our database. All data obtained from the study may be disclosed

through publication in scientific articles. However, all published data will be anonymous, that is, the data will not be linked to your name or to the hospital records.

If you are diagnosed with another condition such as a weak heart (heart failure) or a blood clot in your lung (pulmonary thromboembolism), you will be referred for specific treatment and will not participate in the study.

If any harm occurs as a result of participating in the study, you are guaranteed the right to compensation, in accordance with current legislation in the country.

If you have any questions about the ethical aspects of this research, you may also contact the Research Ethics Committee of the Hospital das Clínicas of the Ribeirão Preto School of Medicine by calling (16) 3602-2228. A Research Ethics Committee (CEP) is made up of a group of people who are responsible for supervising research on human beings that is carried out at the institution and has the function of protecting and guaranteeing the rights, safety and well-being of all research participants who volunteer to participate in the research. The CEP of the Hospital das Clínicas and the Ribeirão Preto School of Medicine is located in the basement of the hospital and is open from Monday to Friday, from 8:00 am to 5:00 pm.

Your participation is voluntary, and you are free to accept or decline participation, without risk or prejudice to your care. You also have the right to withdraw your consent to participate in the study at any time.

After reading this document and clarifying your doubts, if you agree to participate in the study, please write your name, sign and date the document in two copies, in addition to initialing all pages. One of the copies will remain with you while the other will be filed at the study center.

Participant data:

Name:_____, RG:_____,

Address: _____, nº_____,

Neighborhood_____, city _____, Phone: _____

Signature:_____ Date:_____

Contact details of the researcher in charge, in case you have any question later.

Researcher's name:_____

Signature_____ Date:_____

Researcher's contact details: Tel: 16-3602-2631/2706; cell phone: 16-99187-7569

Emails: rosangelavillela@yahoo.com.br; evianna@fmrp.usp.br

Address: Hospital das Clínicas de Ribeirão Preto - Pulmonary Function Laboratory, Avenue Bandeirantes, 1900, Campus USP.

This study was approved by the Research Ethics Committee (CEP) of the Hospital das Clínicas of the Ribeirão Preto School of Medicine – University of São Paulo.

Research rubric	Participant/responsible rubric