

Official ClinicalTrials.gov Title:

**Nebulized Enriched Heparin to Treat no Critical Patients With Sars-Cov-2 - Triple
Blind Clinical Trial**

Brief Title:

Enriched Heparin Anti COVID-19 Trial (EnHanCed)

NCT Number: NCT04743011

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ENGLISH TRANSLATION FORM (LITERAL TRANSLATION)

FREE AND INFORMED CONSENT FORM

BRAZILIAN RESOLUTION NUMBER 466/2012

I INVITE you to participate in the Research Project entitled “HIGH MOLECULAR WEIGHT NEBULISED HEPARIN FOR THE TREATMENT OF SARS-COV-2” which will be developed by me, Professor Matheus Bertanha, (Vascular Surgeon) and Professor Carlos Magno Castelo Branco Fortaleza, both from the São Paulo State University – UNESP. I am studying the SARS-COV-2 disease, also known as coronavirus. In order to find a new effective treatment for it. To have a result at this point, I need to perform laboratory tests with the collection of 10ml samples of your blood, which will be the following tests (Full Blood Test, D-Dimer, Coagulogram, Urea, Creatinine, Total Proteins and Fractions, Blood Glucose, C-Reactive Protein), in addition to performing a rapid test for COVID-19 (IgG and IgM) by collecting a drop of blood from the fingertip, RT-qPCR test requiring nasal swab collection and computed tomography (without contrast) . The risk with blood collection and other tests will be minimal, and a small purple spot may appear at the puncture site, which will disappear very quickly.

I request your consent to consult your medical record in order to collect other information contained therein, such as laboratory exams and images. In addition, you will answer a questionnaire that will take about 15 minutes.

Patients will be divided into two groups, one of the groups will receive the treatment proposed by our research group, with the medication "High Molecular Weight Heparin" by inhalation, while the other group will receive inhalation of saline only, also known as a “control group”, this saline solution will not have any negative effect on the patient.

The disease SARS-COV-2, "coronavirus", can progress to severe forms, even in the presence of the best treatments available, including the treatments proposed to the participants in this study. Any symptoms of aggravation of the disease will be evaluated by the health professionals of the Clinical Hospital of Botucatu, where they will receive all the necessary support in accordance with the treatment protocols for severe forms of the infection.

Your benefit of participating will be the possibility of receiving a promising new treatment for SARS-COV-2, by inhalation. Since at this time, as it is a recent disease, there is still no effective treatment or well-established alternative methods and this treatment may help you and others in the future. We hope, with the research, to establish the safety and effectiveness of this new treatment as a benefit to society.

Please be aware that your participation in this study is voluntary and that even after you have given your consent to participate in the research, you can withdraw it at any time, without any prejudice to the continuity of your treatment.

You will be guaranteed the right to full and free assistance in case of any damages arising from participation in this research and for as long as necessary, including after the end of the study, with follow-up via the infectology ambulatory until cure and total remission of symptoms. You are entitled to seek compensation for any damages arising from this research.

This Informed Consent Form will be prepared in 2 copies of equal content, which 1 copy will be delivered to you, duly initialed, and it is essential that you keep it in your files, with the guarantee that a new copy will be sent by the to the participant, if requested, and the other copy will be filed and kept by the researchers for a period of 5 years after the end of the research. All personal information will be confidential and the participant's privacy will be guaranteed.

If you have any additional questions, you can contact the Research Ethics Committee through the telephone numbers +55 (14) 3880-1608 or 3880-1609, which is open from Monday to Friday from 8:00 am to 12:00 pm and from 1:30 pm to 5:00 pm, at Chácara Butignolli s/nº in Rubiao Junior – Botucatu – Sao Paulo.