

PREDICTIVE FACTORS OF NON-INVASIVE RESPIRATORY SUPPORT FAILURE IN PNEUMONIA BY THE SARS COV-2 VIRUS.

Information sheet and informed consent to participate in the study: PI-20-372

Approved by the Drug Research Ethics Committee of the Germans Trias i Pujol Hospital on: _____

Introduction

We are writing to you, on behalf of the research team led by Irene Aldás Criado and Antonio Marín Muñoz, to inform you about a research study in which you are invited to participate. Your participation is voluntary. Please take the time you need to read the following information and check whatever you want. Ask the investigator of this study if there is anything that is not clear to you or you like more information. The promoter of this study is the Germans Trias i Pujol University Hospital in Badalona. The research center where you will participate is at the *Germans Trias i Pujol* University Hospital in Badalona.

The purpose of the study

Pneumonia caused by the SARS Cov-2 coronavirus is a viral infectious disease that is characterized in some cases by the rapid and progressive respiratory failure of the respiratory system, being the most serious affectation and the one that marks the prognosis. Non-invasive breathing supports are therapies that help you breathe in severe respiratory failure. Therefore, monitoring of respiratory exhaustion should be carried out in all patients with SARS Cov-2 pneumonia. Within this follow-up, prognostic factors could be identified that help to assess with what probability the treatment with these supports may or may not be successful.

We will carry out a prospective, descriptive study at this center in order to assess respiratory clinical variables by telemetry recording and blood tests during follow-up.

To do this, we will carry out, during the follow-up of patients already diagnosed, or with a new diagnosis of SARS Cov-2 pneumonia and respiratory failure, who require non-invasive support therapy, an analysis on the first day of initiation of therapy, at 48 hours and at the end of this therapy, we will also continuously monitor vital signs while these therapies are

used. We will compare the values obtained from patients who only require therapy with high-flow nasal cannulas and from patients who are not sufficient for this treatment and need non-invasive mechanical ventilation.

Participants in this study who do not have sufficient respiratory support with high-flow cannula therapy and feel exhausted, will be switched to non-invasive mechanical ventilation. Each patient will be randomly assigned to one of two possible settings: setting A (continuous pressure mechanical ventilation) or setting B (intermittent pressure mechanical ventilation). This decision is made because to date there are no scientifically proven differences in which configuration is best for the treatment of this disease. The data on the success of the therapies will be compared, understanding as failure the need for orotracheal intubation to perform invasive mechanical ventilation or death.

This research study has been approved by the Research Ethics Committee of the *Germans Trias i Pujol* University Hospital.

Study Procedures and Possible Risks and Discomforts

Vital signs will be recorded during the time that non-invasive respiratory support therapy is performed continuously for the assessment of respiratory status. This does not pose any additional risk, since it is a non-invasive procedure and without exposure to ionizing radiation.

Between 3 and 5 tests will be carried out during the study, which are the same as those carried out in the usual clinical practice of this disease. They pose risks of pain due to puncture and extravasation of a blood vessel.

Participation in this study would not produce any discomfort except those derived from the non-invasive respiratory support therapies themselves. These are: epistaxis, runny nose, excessive noise in the treatment with high-flow cannulas and skin ulcers in the case of non-invasive mechanical ventilation. It does not imply an added risk to that of normal clinical practice for health since an additional intervention will not be carried out.

The information regarding your personal data (initials and medical record number) will be coded, a non-consecutive alphanumeric code will be assigned, which will be called the patient study code. This will only be known to the principal investigators, who will save this data using a password-protected Microsoft Excel file.

The clinical information collected for the study associated with your patient code will be stored in a Microsoft Excel type computer file located at the research center. To access it, you will need a second password different from the first one. These data can only be re-identified by the study's principal investigators or by collaborators authorized by them. They will be used exclusively for the purposes specified here.

Voluntary participation and withdrawal

You can freely decide whether or not you want to take part in this study, participation is completely voluntary. If you decide to participate, you still have the possibility to withdraw at any time, without having to give explanations, and without any penalty or negative consequences for you. If you change your mind regarding your samples or your data, you have the right to request their destruction or anonymization, through your doctor / researcher. However, you should know that the data obtained in the analyzes carried out up to that moment may be used for the purposes requested and may be kept in compliance with the corresponding legal obligations.

Participation in this study is not incompatible with participation in other clinical studies or trials.

Possible benefits

No direct benefit is expected from your participation in the study. However, the information gained from this research project can contribute to medical advancement and could help other patients in the future. You will not receive any economic benefit for the transfer of the data provided, nor will you have rights over possible commercial benefits of the discoveries that may be achieved as a result of the research carried out.

Data protection and confidentiality

All information about your results will be treated strictly confidential. Your personal data will be identified by a code, so that it does not include information that can identify you, and only the research team will be able to relate that data to you. These data will be protected by password. These coded clinical data will be the ones that will be statistically analyzed to search for scientific findings that answer the questions proposed in this study. The analysis of this data will be carried out by the external company BUTLER SCIENTIFICS using Auto-discovery technology. This has signed a confidentiality and data treatment contract with the

promoting center and the study researchers. This company will receive the data by means of a file with a password via email from the promoter center. BUTLER SCIENTIFCS in no case will know identifying data of the study participants. You may only make one research use for this study. You will not be able to trade or use the data for other purposes.

The Germans Trias i Pujol University Hospital - ICS Metropolitana Nord, as promoter and center where the study is carried out, assumes responsibility for data protection. Your personal data will be protected in accordance with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (RGPD, having the right to access, rectify or cancel your data, and can limit the processing of data that are incorrect, request a copy or have the data that you have provided to a third party be transferred to To exercise your rights, contact the study's main researchers or collaborators whose data is specified at the end of this document. You can also contact the Data Protection Department of TIC Salut dpd@ticsalutsocial.cat . You also have the right to to contact the Data Protection Agency if you are not satisfied.

If the results of the study were subject to publication in scientific journals, personal data of the participants in this research will not be provided at any time.

Information on results

In the event that you request it, at the end of the study and in accordance with article 27 of Law 14/2007 on Biomedical Research, information on the results of this research work may be provided to you

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INFORMED CONSENT

**PREDICTIVE FACTORS OF NON-INVASIVE RESPIRATORY SUPPORT FAILURE IN
PNEUMONIA BY THE SARS-COV-2 VIRUS**

I (name and surname) _____

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

I have received enough information about the study.

I have read the informed consent.

I have spoken with principal investigator or co-investigator

I understand that my participation on study is voluntary.

I understand that I can withdraw from the study:

Wherever I want

Without giving explanations

Without negative repercussions

I voluntarily agree to participate in the project and I authorize the use of all the information obtained. I understand that I will receive a signed copy of this informed consent.

Participant Signature

Date: