INFORMATION AND INFORMED CONSENT SHEET

Title	MP3-pulses COVID-19. METHYLPREDNISOLONE PULSES VERSUS DEXAMETHASONE RECOVERY REGIMEN IN PATIENTS WITH PNEUMONIA DUE TO SARS-COV-2 CORONAVIRUS INFECTION
Protocol Code	MP3-pulses-COVID-19
Principal Investigator	
Service	

Introduction

We are writing to inform you about a research study in which you are invited to participate. Participation is voluntary. Please take the time to read the information below and refer to what you want. Ask the researcher in this study if anything is unclear to you or if you want to learn more.

As you know, he is hospitalized for a confirmed condition or very compatible with coronavirus infection.

This is still a poorly understood disease. So far, there is no treatment specifically directed against this virus. However, there are several medications that have been found to be effective in some patients. These treatments, and other general measures, are being administered to you, in a way that is tailored to your clinical situation.

After infection with the virus, the body's defense systems organize a response to try to eliminate it. That response sometimes leads to inflammation of some organs, especially the lungs. For this reason, medications, such as corticosteroids, are sometimes used in this disease to try to decrease the harmful part of the inflammation.

At the end of June 2020, a large clinical trial (RECOVERY) conducted by the British public health system was the first to clearly demonstrate that corticosteroids are useful in the management of this disease when patients notice shortness of breath and require supplemental oxygen. Since then, this treatment has been common in all patients with COVID-19 pneumonia.

However, even though we know the usefulness of corticosteroid treatment, we still need to know what the ideal dose and duration of treatment is and whether the use of higher doses could be even more beneficial for the patient.

Objective of the study

The aim of the study is to compare the effect of high-dose methylprednisolone boluses versus the dexamethasone intermediate-dose regimen (the one used in the RECOVERY trial) in COVID-19 patients with non-critical respiratory failure.

This research study has been approved by the Ethics Committee for Research with Medicines of the Salamanca Health Area and is carried out in accordance with current legislation, Royal Decree 1090/2015 of 4 December and European Regulation 536/2014 of 16 April, which regulate clinical trials with medicines. and in accordance with the standards of good clinical practice.

Study Procedures and Potential Risks and Discomforts

The study will compare the outcome of a limited number of patients divided into 2 groups. Both groups will be treated with glucocorticoids. One of them at the dose tested in the RECOVERY trial for 10 days. The other group will receive higher doses, but for only three days, known as methylprednisolone boluses.

The study has been reviewed and approved by the appropriate committees in order to ensure its quality and the safety of the patients included.

During the study, your doctor will inform you of the need to receive steroid treatment. You will then be assigned to one of two study groups:

1) Group 1: dexamethasone 6 mg for 10 days, the first three intravenously and the rest either orally or intravenously depending on the patient

2) Group 2: 3 boluses of intravenous methylprednisolone. You will also continue with all other treatments indicated for your particular case.

This assignment will be made 1:1 randomly, you have an equal chance of getting one or the other treatment arm. In addition, the assignment is done centrally, so neither you nor the doctor know a priori the branch of treatment that you may have.

Your doctor will monitor your progress and may always modify the treatment, or cancel the study, if he or she considers it preferable in terms of your evolution. Subsequently, you will collect the main data from your story to analyze the results. That data will be encrypted, with no possibility of you being identified.

The rest of the treatment will be included in your hospital's COVID-19 management protocol. No diagnostic laboratory or imaging tests other than those that would normally be performed during the admission of a patient with COVID-19 infection will be performed. During admission, you will have at least 2 x-rays and 3 analysis determinations.

In addition, 28 days after the start of treatment, a follow-up visit will be made to see your progress, in which some more tests will be carried out, such as blood tests and imaging tests. Similarly, at 12 weeks or if you are removed from the study, of your own volition or by decision of your doctor, prematurely at any time during your participation, you will have another follow-up visit. This visit can be carried out in person or by phone, if the doctor and you consider it appropriate, so, in addition to asking you about your condition, you could be given some more tests such as blood tests and imaging tests if the visit is face-to-face.

Given the current situation of the global health crisis, in the event of a lack of stock of any of the active ingredients in the study, it could be decided to use other glucocorticoid preparations in doses equivalent to that of methyl-prednisolone, according to the following table:

Active ingredient	Guideline	Equivalence in methyl-prednisolona	Equivalence in prednisone
Dexamethasone	6 mg/24h	30 mg/24h	37.5mg/24h
Methylprednisolona	250mg/24h	N/A	312.5 mg/24h
Hydrocortisone	50-100mg/6h	20-40 mg/12h	25-50 mg/12h

In both arms of the study, or in the case of administering any of the other glucocorticoid preparations, the risks inherent to the use of corticosteroids may appear, such as mainly the increased risk of infection added to the infection by the virus itself (rare), increased blood glucose levels (rare) or mood disorders (very rare). Other side effects of corticosteroids such as high blood pressure, dyslipidemia, diabetes or osteoporosis are not expected in this study given the short duration of treatment. Participation in this study would not cause any discomfort, and does not involve additional health risk.

If you do not agree to participate, your doctor will continue your current treatment and may eventually consider administering the 10-day dose of dexamethasone as well.

Voluntary Participation and Withdrawal

You are free to decide whether or not you want to take part in this study, participation is completely voluntary. If you choose to participate, you still have the ability to withdraw at any time, without explanation, and without any penalty or negative consequences for you. If you change your mind about your data, you have the right to request its destruction or anonymization, through your doctor/researcher. However, you should be aware that the data obtained in the analyses carried out up to that point may be used for the purposes requested and may be kept in compliance with the corresponding legal obligations.

If you do not participate in the study, you will receive treatment according to standard clinical practice, and there is even the possibility that, if your doctor decides to do so, you may receive one of the drugs offered in this study. If you want, the study doctor will give you more information.

Potential Benefits

You may not get any health benefits from taking part in this study. However, the information gained from this trial may contribute to medical progress and could help other patients suffering from their disease in the future.

You will not receive any financial benefit from the transfer of the data provided, nor will you have rights to possible commercial benefits from the discoveries that may be made as a result of the research carried out.

Data protection and confidentiality

All information about your results will be treated as strictly confidential. Both the Centre and the Promoter are responsible for the processing of your data and undertake to comply with the data protection regulations in force, currently Organic Law 3/2018, of 5 December, 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 (GDPR). The data collected for the study will be identified by a code, so that no information that could identify you is included, and only the research team will be able to relate this data to you. The research team will analyse your data based on the legitimate interest of achieving the purposes of the study. Subsequently, your personal information will only be retained by the health care center and the research team for other scientific research purposes if you have given your consent to do so and if permitted by applicable law and ethical requirements.

If the results of the study are susceptible to publication in scientific journals, at no time will personal data of the participants in this research be provided. We inform you that you have the right to access, rectify or cancel your data, and you can limit the processing of data that is incorrect, request a copy or transfer to a third party of the data you have provided for the study. To exercise their rights, or in the event that the participant wishes to provide further information on the processing of their personal data, the principal investigator of the study whose details are specified at the end of this document may be contacted by the Data Protection Officer of the Regional Health Management (dpd@saludcastillayleon.es) or our centre (dpd.husa@saludcastillayleon.es). You also have the right to contact the Data Protection Agency if you are not satisfied.

Information on results

At your request, at the end of the study and in accordance with article 27 of Law 14/2007 on Biomedical Research, you may be provided with information on the results of this research work.

I authorize those responsible for the project to use my data for the purposes and in the manner described in this document.

□ IF □ NO

I consent to the future use of the data that have been collected in this research study to conduct other research related to the medical specialty or research area of this study

□ IF □ NO

I consent to my medical records being accessed again in the future to collect data that is considered important for other research related to the medical specialty or research area of this study

□ IF □ NO

Contact details of the research team:

If you have any questions or need more information, please contact:

Name:

Telephone:

INFORMED CONSENT

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Principal Investigator	
Service	

I *(First and Last Name)* _____

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

I've been able to ask questions about the study.

I have received enough information about the study.

I have spoken with the Investigator _____

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1º Whenever you want

2º Without having to give explanations

3º Without having any negative repercussions

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

_____ _____

Participant's signature Date

_____ _____

Researcher's name and signature Date

INFORMED CONSENT IN THE PRESENCE OF A WITNESS*

Title	MP3-pulses COVID-19. METHYLPREDNISOLONE PULSES VERSUS DEXAMETHASONE RECOVERY REGIMEN IN PATIENTS WITH PNEUMONIA DUE TO SARS-COV-2 CORONAVIRUS INFECTION
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_____

(Patient's name and surname)

I *(Name and Surname of Witness)*_____

I confirm that the patient has read (or has been read to them if they are unable to do so on their own), the information sheet that has been given to them about the study.

He was able to ask questions about the study.

You have received enough information about the study.

Have you spoken with the Investigator _____

You understand that your participation is voluntary.

You understand that you may withdraw from the study:

1º Whenever you want

2º Without having to give explanations

3º Without having any negative repercussions

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

_____

Signature of the witness
Date

_____

Researcher's name and signature Date

***When the patient is unable to sign and gives oral consent. The witness may be a family member or healthcare worker.**

INFORMED CONSENT FOR LEGAL REPRESENTATIVE

Title	MP3-pulses COVID-19. METHYLPREDNISOLONE PULSES VERSUS DEXAMETHASONE RECOVERY REGIMEN IN PATIENTS WITH PNEUMONIA DUE TO SARS-COV-2 CORONAVIRUS INFECTION
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_____

(Patient's name and surname)

I *(Name and Surname of Legal Representative)* _____

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

He was able to ask questions about the study.

You have received enough information about the study.

Have you spoken with the Investigator _____

I understand that your participation is voluntary.

I understand that you may withdraw from the study:

1º Whenever you want

2º Without having to give explanations

3º Without having any negative repercussions

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

_____

Signature of the legal representative Date

_____

Researcher's name and signature Date

INFORMED CONSENT IN THE PRESENCE OF A WITNESS*

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_____

(Patient's name and surname)

I *(Name and Surname of Witness)*_____

I confirm that the patient has read (or has been read to them if they are unable to do so on their own), the information sheet that has been given to them about the study.

He was able to ask questions about the study.

You have received enough information about the study.

Have you spoken with the Investigator _____

You understand that your participation is voluntary.

You understand that you may withdraw from the study:

1º Whenever you want

2º Without having to give explanations

3º Without having any negative repercussions

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

_____

Signature of the witness
Date

_____

Researcher's name and signature Date

REVOCATION OF CONSENT

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D/Dña ____

I voluntarily revoke the consent given on _____

_____ _____

Participant's signature Date

_____

Researcher's name and signature Date