Prolonged Low Doses of Methylprednisolone for Patients With COVID-19 Severe Acute Respiratory Syndrome

NCT04323592

March 23rd, 2020

Informed Consent form for patient (English version)

TITLE: "Efficacy of Methylprednisolone for Patients With COVID-19 Severe Acute Respiratory Syndrome"

Internal protocol numb.: 023_2020H version 01 dd. 17/03/2020

PROMOTED BY: ASUGI - Azienda Sanitaria Universitaria Giuliano Isontina – S.C. Pneumolgia

PRINCIPAL INVESTIGATOR: prof. Marco Confalonieri

Contacts of principal investigator: Prof. Marco Confalonieri (email mconfalonieri@units.it, tel.0403994667)

Version n. 01, 16/03/2020

Dear patient,
with this informed consent you are invited to participate in this no profit clinical research. The title of our research project is "Efficacy of Methylprednisolone for Patients With COVID-19 Severe Acute Respiratory Syndrome" promoted by ASUGI - Azienda Sanitaria Universitaria Giuliano Isontina – S.C. Pneumolgia, Head prof. Marco Confalonieri.
The principal Investigator (PI) of the research is Prof. Marco Confalonieri (email mconfalonieri@units.it, tel.0403994667), Head of the Center above.
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier. You will know any new information that may change your decision to participate in this clinical study.

Purpose of the research
In the actual urgent situation, this prospective observational study has the propose to investigate the efficacy of the drug named: methylprednisolone (MP), which will be administrated in low dose prolonged infusion in severe acute respiratory syndrome (SARS) with ARDS caused by COVID-19, as you are affected.
A recent study published on an important scientific paper (JAMA Intern Med) showed impressive positive effect of methylprednisolone (MP) on survival of SARS-CoV-2 critically ill patients.
This study is a multicentric study, conducted at more than one pneumology center and respiratory intensive care unit.
In this clinical study we will administrate methylprednisolone first in low dose prolonged infusion and then orally, slowly reducing the dosage until a maximum period of 1 month.
This study wants to enroll 104 patients, whom 52 treated with methylprednisolone and comparing them in the same conditions with patients not treated with methylprednisolone. You would be included in the arm of treatment with methylprednisolone. If you decide to participate in this study you will have a follow-up in the sole interest to monitor how are you feeling and how the usual blood tests are going.

Risks and side effects
Methylprednisolone may cause many of the most common side effects correlated with the other corticosteroids (gastric symptoms, irritability, weight gain, osteopenia, hyperglycemia). But in case of side effects we can resolve them by reducing further the dosage of methylprednisolone.
In other studies on viral pneumonia, a correlation between corticosteroids treatment and fatal event is never be found.

Benefits

If you participate in this research, you will have the following benefits: if you will be treated with methylprednisolone our expectation is a reduction in risk of mortality and a decrease in needing of ICU admission and intubation, according to the results of the recent published clinical study on the effect of methylprednisolone in severe infections caused by SARS-CoV-1.

Alternatives to Participating
COVID-19 is a new widespread virus, and the entire scientific community around the world are working on finding new cure. Through this study, we are trying to find an effective cure. There are not alternatives for this purpose at the moment.

Clinical Trial Insurance
Copertura Assicurativa Polizza RCT Aziende SSR apr2017-apr2020

Rights of the patient
It will be guaranteed the amount of time you need to decide whether or not you will participate in the research.
If you have questions, you can ask them of us in any time and we will give you all the explanations you need.
You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose, without any kind of explanations. It is your choice and all of your rights will still be respected. Your participation is free.

Confidentiality
We will not be sharing the identity of those participating in the research. The information that we collect from this research project will be kept confidential. The information will be collected. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key.

All the information collected during the study are confidential and will be concerned in compliance with the following regulations:
REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.
Regulation (EU) No 536/2014 of the European Parliament on clinical trials on medicinal products for human use

<u>If the patient doesn't authorize the process of his/her personal details, he/she can't participate in the study.</u>

Possibility for the patient to request communication and information about results of the study
For any kind of information you can contact the principal investigator: Prof. Marco Confalonieri (email mconfalonieri@units.it, tel.0403994667), Head of SC Pneumologia, Cattinara Hospital, Trieste.

Other information
We inform you that the protocol of the study, that we have proposed you, is conformed to Directive of Good clinical practice (EU) and to the current revision of Helsinki Declaration. The protocol has been approved by the Ethics Committee of Friuli Venezia Giulia – Italy (Comitato Etico Unico Regionale del Friuli Venezia Giulia), by health authority holding jurisdiction or designated institutions.

Principal Investigator

Prof. Marco Confalonieri (email mconfalonieri@units.it, tel.0403994667), Head of SC Pneumologia, Cattinara Hospital, Trieste.

Certificate of Consent

PATIENT _____ _____ *(Print Name and Surname)*

The undersigned (Print *name and Surname*) _____ _____,

Born in _____ the: __/__/_____

resindent in _____city _____ postal code _____

street _____n° _____Tel. _____

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

I declare:

- To have had sufficient time to think about the information I received to take freely a decision and to have had the possibility to discuss about it with the researcher, family or my GP;
- To have understood the purpose of the study and the treatment I will do;
- To be free to refuse to participate in the research, without any kind of explanation and without losing my medical and legal rights;
- To be free to decide to participate in the study, and to know that I can decide to stop participating in the study at any time, without any necessary explanation.;
- To consent that the Ethical Committee can have the access to my clinical data.
- To be aware that the results of the study will let be known to the scientific community and that my identity will not be mentioned in any results, and every collected information will be collected as confidential;
- To consent the acquisition, elaboration, analysis and communication in some publications of my confidential data and clinical information collected during the study and elaborated in anonymous form.

I understand that I will receive a copy of this document. The original document will remain to the study center. The validity of this consent will last until I will not revoke it.

I AGREE - DO NOT AGREE: to participate in the study.

I AGREE - DO NOT AGREE: that the researcher will inform my general practitioner about my participation in the study.

I AGREE - DO NOT AGREE: to be informed by the researcher medical doctor on the results of the study.

Print Name of the patient:

_____ _____

Data: _____

Sign of the patient:

_____

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the modalities of the study.
I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Date: _____

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

A copy of this ICF has been provided to the participant.