PROVID-19 Version 2.0 on 21/09/2020

Impact of Prone Position in Patients Under Spontaneous Breathing on Intubation or Noninvasive Ventilation or Death Incidence During COVID-19 Acute Respiratory Distress (PROVID-19 trial)

Research Promoter: Orleans Regional Hospital, 14 avenue de l'Hôpital 45067 Orléans

Coordinating investigator: Dr Mai-Anh NAY, Intensive Care Unit

Invitation

You are currently hospitalized with a COVID-19 infection that required specific management.

As part of this management, you are under oxygen, to improve the level of oxygen in your lungs and blood. In the context of the COVID-19 infection, we believe that prone position may improve your respiratory condition. However, prone position has never been proven or studied in COVID-19 patients.

Our study would assess the benefits of prone positioning compared to usual care (i.e semi-sitting in a bed or sitting in a chair).

You are invited by Doctor …… (Name, First name) to participate in a research study named "Impact of prone position in patients under spontaneous breathing on intubation or noninvasive ventilation or death incidence during COVID-19 acute respiratory distress". The study is promoted by the Orleans Regional Hospital, , CS 86709, 45067 Orléans Cedex 02, 02.38.51.44.44).

Time to think

This information sheet allows you to decide whether you want to participate in this study.

Please read this document carefully. If you have any doubts or do not understand, you can ask questions to the person who has just given you this document.

Participation in this study is based solely on your voluntariness. In the case that you do not want to participate, the health care team will continue to treat you with the best treatment with the best techniques currently used.

Rational of the study

Prone position has shown benefits in a critically ill patients who suffered from an acute respiratory distress syndrome without COVID-19. One of the most common complications of COVID-19 is respiratory complications.

In medical wards, the usual care for patients is to be in a semi-sitting position in bed or sitting in a chair on daytime period.

We believe that for COVID-19 patients, under oxygen who have just been admitted to the medical ward, that prone position would improve respiratory status compared to usual care.

Up to now, no study has compared these two positions either in the context of the pandemic

COVID-19 on medical wards. We don't know which it the best position to improve ventilation.

<u>Conduct of the study</u>

Your participation in the study will last either until the end of your stay if it lasts less than 28 days, or until the 28th day if your stay extends beyond that. If you agree participate in this study, a randomization will determinate if you will have sessions of prone position (intervention group) or usual care, i.e semi-sitting in bed or sitting in a chair if you wish (control group).

The person who proposes you to participate in this study cannot know in which group you will be randomised, until your acceptation to participate and the randomisation process.

1- Intervention group: Prone position

You will have to position on prone position alone or with minimal assistance. We ask you to perform a minimum of two sessions on daytime with a minimum of total cumulated time of 2h30. The objective is to spend as much time as possible on prone position if you can tolerate. We encourage you to sleep during the night as much as possible on prone position.

For your safety, bed rails will be placed to prevent the risk of fall of the bed.

You will have to note at each session (in a notebook that we will provide) the time of the beginning of the prone position during the daytime. This notebook can be filled by yourself or by a member of the medical or paramedical staff taking care of you.

If you don't feel comfortable, you can turn your head to one side or the other and keep your arms in the most comfortable position as possible. The objective is that your back don't touch the bed.

If, despite your attempt to get more comfortable, you still do not feel comfortable breathing, you can return to semi-sitting position in bed. The call bell will be given to you before prone position so that you can contact the staff if necessary.

In any case, you will have to note the time of the end of your prone position.

This position will be carried out at least twice a day with the objective of a minimum cumulative duration of minimum of 2.5 hours on daytime.

2- Control group: Semi-sitting in bed or sitting in a chair

If the randomisation determine that you will be in the control group, you will have to stay in semi-sitting position in bed or sitting in a chair on daytime during your hospital stay with a maximum of 28 days.

If possible, you should not position on prone position except for sleep on night if it is your natural position for sleeping.

For both groups, you will be able to walk in your room.

What are the possible benefits of the study?

The benefits will be to show that the sessions of prone position compared to the conventional position alone, for patients with a COVID-19 infection, would improve respiratory status. If the results of the study are positive, this will improve the management of COVID-19 patients on medical wards.

What are the possible disadvantages?

Potential risks of the prone position are asthenia, respiratory discomfort, an increase of heart rate, a decrease of oxygen level measured by the sensor to your finger. All of these are common in COVID-19 patients in case of aggravation of the disease. Hospitalization in specific wards can reduce these risks. For patients who will require prone position, the start and end time of each position should be recorded. These sessions should be repeated throughout the hospital stay in the medical ward, up to a maximum of 28 days if the hospitalization goes that far.

Information on alternatives

If you refuse to participate in this study, you will benefit of usual care on positioning in the medical ward where you are hospitalized.

Retrospective and ancillary studies

Your data that was collected during the research will be used for the purposes of the research. At the end of the study, we would like to keep your data, unless you object, in order to use it for other retrospective studies up to 15 years after the end of this study.

Voluntary Participation

Your participation in this research is completely voluntary and will not result in any additional financial cost to you. The intervention technique, the prone positioning, if you are included in the prone positioning group, will be applied to you daily until the end of your hospitalization in the medical ward and for a maximum of 28 days. The duration of the research (which, beyond the 28th day, will consist of collecting information on your evolution) will be until your discharge from the hospital, or until the 28th day if your hospitalization ended before.

You are free to accept or refuse to participate, you are free to change your mind at any time and to withdraw your consent without having to justify it. Your decision will not prejudice the quality of the management of your disease. Your data collected during the research will only be analysed if you give your consent.

Your attending physician may be informed by letter mail of your participation in the study if you wish. If you do not wish to participate in this study, you will receive the usual care.

If the study is terminated prematurely or if your participation is interrupted, you will receive the usual care currently provided in the unit where you are being treated and the study data will be analysed.

You may discontinue your participation at any time.

Additional information

Dr Mai-Anh NAY (CHR Orléans - Intensive Care Medicine Department - 14 avenue de l'hôpital, CS 86709, 45067 Orléans Cedex 02) will be able to answer all your questions about the PROVID-19 study at any time. He can be reached at the following telephone number: 02.3XXXXXXX

Privacy, Data Collection and Use

Within the framework of the research whose purpose meets the criteria of public interest in which the CHR ORLEANS proposes that you participate, your personal data will be processed electronically to enable the results of the research to be analysed in the light of the objective of the research which has been presented to you.

This processing complies with the regulatory provisions allowing a health establishment to process data for scientific research purposes (art. 9.2 RGPD). The person in charge of this processing is the CHR ORLEANS, promoter of the research. In accordance with the European Data Protection Regulation (RGPD), the CHR ORLEANS has appointed a data protection officer whom you can contact at the following e-mail address: dpo@chr-orleans.fr

To this end, your medical data will be transmitted to the research sponsor or to persons or companies acting on its behalf, in France or abroad. This data will be identified by a code and/or your initials. This data may also be transmitted, under conditions that ensure their confidentiality, to French or foreign health authorities and to other entities of the CHR ORLEANS. The CHR ORLEANS, in the context of future collaborations, may also transfer this coded data to institutional or industrial scientific teams in France or elsewhere in the world in order to continue research on the subject or for scientific research purposes in accordance with paragraphs i and j of article 9.2 of the RGPD.

In addition, in accordance with the provisions of the law relating to data processing, files and freedoms (Act of January 6, 1978 as amended), and the European Regulation 2016/679 of April 27, 2016 (RGPD), you have the right to access, rectify, portability and limitation of your personal data at any time. You may also lodge a complaint with a supervisory authority (CNIL for France) You also have the right to

object to the transmission of data covered by professional secrecy that may be used in the context of this research and be processed. The exercise of this right requires the withdrawal of your consent to participate in the trial. In this case, the data obtained before the withdrawal of consent will be used in the research.

During or at the end of the research, you can access all your medical data directly or through the intermediary of the doctor of your choice in application of the provisions of article L1111-7 of the public health code and the European Union's RGPD n°2016/679. These rights can be exercised with the doctor who is following you in the context of the research and who knows your identity or with the Data Protection Delegate of the ORLEANS Regional Hospital.

Your data will be kept for the duration of the research. After the end of the research, the data will be archived for a period in accordance with the regulations (minimum 15 years), then destroyed.

Overall results of the study

At the end of the research and after analysis of all data related to the study for all patients, you will be informed of the overall results of the study through the physiotherapist or doctor or nurse who followed you in the framework of this research in accordance with Article L.1122-1 et seq. of the Public Health Code.

A description of this study will be available in the directory http://www.clinicaltrial.gov. A summary of the results will be published on this site. Access to this site is free and no data that could identify you will be published.

Ethics committee favourable opinion

In accordance with the public health code and decree n°2017-884 of May 9, 2017,

This research obtained an initial favourable opinion from the West VI Committee for the Protection of Persons on 24/04/2020, a favourable opinion for MS1 on May 12, 2020 and a favourable opinion for MS2 (this version) on October 7, 2020.

Insurance

The promoter of this research, CHR ORLEANS, 14 avenue de l'hôpital, 45067 Orléans Cedex 2, has taken out civil liability insurance with SHAM. Contract N° 141.XXXX.

Obtaining consent

After reading this information note, do not hesitate to ask your physiotherapist or doctor or nurse any questions you may have. After a period of reflection, if you agree to participate in this research, the investigator will collect your free (without constraint), informed (having had all the explanations), and express (you have expressed your agreement to participate in this research) consent.

The investigator will provide you with a copy of the complete document as well as the copy dated and signed by the investigator, justifying your participation in the study.