Patient information sheet:

STUDY TITLE: Personalized masks in non-invasive mechanical ventilation: an innovative approach using 3D printing CEIM: 23/478

PRINCIPAL INVESTIGATOR: Javier Sayas Catalán, Pulmonology Service, 12 de Octubre University Hospital.

INTRODUCTION

The investigators are writing to inform you of a research study in which you are invited to participate. The study has been approved by the Research Ethics Committee of the 12 de Octubre Hospital in accordance with current legislation, the Biomedical Research Act of 3 July 2007.

Investigators intention is that participants receive correct and sufficient information to enable them to evaluate and decide whether they wish to participate in this study. To this end, please read this information sheet carefully, and the investigators will clarify any doubts that may arise after the explanation. In addition, participants will be able to consult with whomever they deem appropriate.

VOLUNTARY PARTICIPATION

Participants should be aware that their participation in this study is voluntary and that they may decide not to participate or change their decision and withdraw their consent at any time without affecting their relationship with their doctor or their treatment.

OVERVIEW OF THE STUDY

THE PURPOSE OF THE STUDY

What The researchers want to find out is whether the use of a mask specially designed to fit the face and anatomy of the participants can improve the quality of use of the participants' mechanical ventilation device. In particular, if it can improve air leakage.

STUDY DESCRIPTION

The trial is aimed at patients with chronic obstructive pulmonary disease (COPD) who require a ventilator at home for several hours a day and/or night for an indefinite period of time, and patients with neuromuscular diseases who also require the use of a ventilator. It is aimed at patients who regularly use a ventilator for at least 4 hours/night.

What The researchers want to find out in this trial is whether the use of a personalised mask, specially designed to take into account the particular anatomy of the participant's face, can improve the amount of air that escapes due to poor mask fit and other characteristics related to the use of the ventilator.

To do this, the investigators need to scan (like "photograph") the participant's face with a device that takes multiple photographic images simultaneously, completely harmless, without contact and without relevant radiation. Once the image of the participant's face has been taken, a personalised design will be made and the mask will then be printed in medical grade silicone, similar to the commercial mask that the participants normally use.STUDY ACTIVITIES

The study will last 8+2 weeks in total, during which time participants will attend 4 visits.

- At the first visit, the participant's respiratory data from the previous month will be stored, the investigators will take an image of the participant's face using a hand-held scanner (a procedure similar to taking a photograph, estimated to take 1 or 2 minutes).

- During the next The investigators ek or two The investigators eks, the pre-fabricated mask will be available and participants will be scheduled for a second visit to check the fit of the mask and deliver it to the participants. During the following month, participants will be allocated to one of the study groups, which will determine whether participants start treatment with one programme or the other.

- Third visit: After one month of using the personalised mask, a validated questionnaire will be used to ask participants about their experience of using the mask, respiratory data will be collected and a sleep study will be scheduled for that night. The next morning, the commercial mask that the participants had before entering the studio is used again.

- After one month of using the commercial mask, participants will return to the hospital to complete a validated questionnaire asking for their opinion on the use of this mask, to collect the respiratory data, and to schedule a sleep study that night in the hospital with the commercial mask.

No other complementary examinations will be performed during the study. As a mould of the participant's mask will be made at the end of the study, the investigators will be able to provide participants with spare parts for this mask for at least the next year, if participants decide to continue using it..

BENEFITS AND RISKS OF TAKING PART IN THE STUDY

At the end of the study, if participants wish to continue using the personalized mask, the investigators will offer to maintain it for at least one year.

During the study period, participants may experience the following symptoms or adverse effects Discomfort with the new personalized mask or problems with any of its components

(although the same medical grade silicone will be used as the participant's commercial mask).

CONFIDENTIALITY

The promoter/researcher undertakes to comply with Organic Law 3/2018 on the Protection of Personal Data and the 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 coded so that it does not contain information that could identify participants, and only the participant's study physician/collaborator will be able to associate the data with the participant and the participant's medical history. Therefore, the identity of participants will not be disclosed to anyone except in cases of medical emergency or legal requirement (if there is a specific situation where it is necessary to know the identity of the subject in order to comply with a requirement of the study, it must be explained in this document). The processing, communication and transfer of all participants' personal data will comply with the provisions of this law.

Access to personal data of the study participants will only be available to the study doctor, collaborators, health authorities, and the Research Ethics Committee. Authorized individuals may access the information solely for data verification and study procedures, while strictly adhering to confidentiality as mandated by current legislation.

The information will be stored in a research file centrally and only used for this study.

Members can access, change, or stop their data according to data protection laws by contacting their doctor for the study.

If a participant chooses to withdraw their agreement to take part in this investigation, no new information will be added to the database, but the data already obtained will be used.

OTHER RELEVANT INFORMATION

If participants decide to withdraw consent to participate in this study, no new data will be added to the database.

By signing the attached consent form, participants agree to comply with the study procedures outlined to participants.

Informed consent

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I, Mr./Ms.,……(name and surname of the father/mother or guardian), residing at ....and DNI number..... ..... I declare that

I have read the information sheet that was given to me.

I have been able to ask questions about the study.

I have received enough information about the study.

I have spoken with:

....

(name of researcher)

I hereby freely agree to participate in the study and give consent for the use of my data.

I understand that participation is voluntary.

I understand that I can withdraw from the study:

- Voluntarily
- Without having to give explanations.
- Without this affecting participants medical care.

Patient Signature: Investigator Signature:

Name: Name:

Date: Date: