Informed consent: PRESERVING LUNG VOLUME DURING EXTUBATION. RANDOMIZED CLINICAL TRIAL. Version 2. August 26th 2022.

Introduction:

During admission to the Intensive Care Unit (ICU) your family member has required mechanical ventilation and currently your doctor considers that it could be withdrawn.

To wean mechanical ventilation, a spontaneous breathing trial is usually performed. There are different validated breathing tests, but the superiority of any of them over the others is not defined.

We propose you to participate in a clinical study in which two different spontaneous breathing tests will be compared.

Objective:

The objective of the study is to define whether a spontaneous breathing test with positive pressure (PEEP) for 30 minutes and without aspiration is more successful in weaning from mechanical ventilation than the test without positive pressure and with aspiration (standard).

Procedure description:

If you agree to participate in this clinical study, your relative will be randomly assigned in a controlled manner to one of the two spontaneous breathing tests of the study. If you successfully complete the test, the endotracheal tube will be removed as usual.

It may happen that despite having passed the breathing test and being extubated, your family member cannot sustain sufficient spontaneous breathing. Reasons may be labored breathing, inability to cough, or impaired consciousness (such as delirium). If this is the case, your attending physician will decide whether to use other rescue techniques (non-invasive ventilation or high-flow oxygen therapy) or whether to reintubate and reconnect you to mechanical ventilation.

Voluntary nature of participation:

Participation in this study is voluntary and you have the possibility to withdraw from it at any time without giving any reason and without prejudice to your treatment or your relationship with the medical or nursing staff. If the principal investigator or his/her responsible physician considers it necessary, the patient may be withdrawn from the study. In case of voluntary abandonment, all his data will be destroyed and will not be included in subsequent analyses.

Confidentiality:

Any data that may be related to an identified or identifiable natural person is personal data and, therefore, remains within the scope of Organic Law 03/2018, of December 5, and Regulation (EU) 2016/679. of the European Parliament and of the Council, of April 27, 2016, on the protection of natural persons in relation to the processing of personal data and the free circulation of such data ("General Data Protection Regulation" or "RGPD") , fully applicable as of May 25, 2018.

In accordance with the rights conferred by current regulations on the Protection of Personal Data, the patient may exercise their rights of access, rectification, limitation of treatment, deletion, portability and opposition, directing their request to the principal investigator of the study or to the Data protection delegate (dpd@althaia.cat).

From the Legal Unit of the Althaia Foundation, Xarxa Assistencial Universitària de Manresa we will resolve all doubts, complaints, clarifications, suggestions and we will attend to the exercise of rights through the email dpd@althaia.cat. We remind the patient that the data cannot be deleted even if they stop participating in the trial to guarantee the validity of the research. He also has the right to contact the Data Protection Agency if he is not satisfied.

Possible benefits:

Your family member will not benefit directly from participating in this study. However, his involvement may help design better mechanical ventilation weaning strategies in the future.

You can obtain more information from the Principal Investigator of the study: Dr. Carles Subira Cuyas (Hospital Sant Joan de Deu de Manresa) at tel. 938732112 ext 3216.