Relationship between the Severity of Bronchiectasis and Exercise Capacity after a Pilot Program for Home Respiratory Rehabilitation at the Virgen Macarena University Hospital

C.P. SCHNR15 - C.I. 1550-N-17
May 07, 2018

Informed Consent Form

Study:
"Assessment of the effects of pulmonary rehabilitation home based program in patients with bronchiectasis at Virgen Macarena University Hospital"

We would like to invite you to participate in the study, through this document we explain what you sew.

This document serves for you to give your consent to participate in this study and the tests that this entails, that means that you authorize us to carry them out. You can withdraw this consent at any time. Signing it does not oblige you to do any type of test if you consider it so. Your refusal will not result in any adverse consequences regarding the quality of the rest of the care received. Before signing, it is important that you read the following information slowly.

What are the objectives and what is the study about?

Our goal is to assess the exercise capacity you have and relate it to the severity of your disease by means of already validated clinical scales.

After your consent, you will be randomly assigned to an intervention group or a control group. This means, if assigned to the intervention group, they will undergo a home rehabilitation program for 8 weeks consisting of aerobic and cardiopulmonary exercises under advice during visits to the respiratory rehabilitation gym by an expert rehabilitator, which will then have to be continued. at home and, if assigned to the control group, they will be taught and given some recommendations and tables of home exercises to be carried out without supervision for 8 weeks

Regardless of the group in which you participate, during the study you will be asked to answer different questionnaires about health and well-being, bronchiectasis, anxiety, cough, nutritional status, among others, which will be recorded in forms that contain a format pre set. The degree of physical activity will be assessed through a device called an accelerometer. Spirometry will be done, which involves blowing through a tube and measuring your lung function. In addition, a cardiopulmonary effort test will be carried out, this is done by pedaling on a stationary bicycle and breathing through a mask to assess your functional capacity for exercise. A 6-minute walk test will also be performed, which consists of walking for 6 minutes down a corridor with a pulse oximeter (to see the levels of oxygen saturation in the blood) and the distance traveled in this time is assessed together with the saturation of oxygen. In addition, their nutritional status will be assessed and anthropometric measurements will be taken before and after the home rehabilitation program. All tests will be repeated before the start of the program, at 8 weeks, 6 and 12 months.

Benefits of your participation in the study

This study will give us information about your exercise capacity and how it can be related to the severity of your disease (bronchiectasis).

On the other hand, respiratory rehabilitation (RR) helps the functional recovery of people with heart disease, lung disease (COPD, bronchiectasis, lung transplant) and/or the circulatory system (peripheral artery disease). The objective of PR is to improve your tolerance to exercise and your quality of life, reducing symptoms such as dyspnea (shortness of breath), chest pain, expectoration, recurrent respiratory infections. It helps fight anxiety and depression and increases enthusiasm and optimism. Helps to fall asleep and improve your quality of life. It decreases the risk of death and increases life expectancy.

Description of the treatment

Respiratory Rehabilitation programs (PRR) consist of a treatment where the doctor and rehabilitator and/or physiotherapist will teach you how to perform the exercises that you will perform at home, as well as the techniques to improve your breathing and to eliminate secretions.

General risks

Any medical action has its risks, however these in most cases do not materialize, however, it is important that you know what risks could arise: Increased dyspnea (shortness of breath) or cough, or dizziness after performance of spirometry as it involves an effort, passing after a few minutes.

During the cardiopulmonary stress test your heart will race, it will become more and more difficult for you to breathe and you will end up tired, you may have a high spike in blood pressure, such as when you do some type of exercise at a sports level.

In the rehabilitation program, cardiovascular or musculoskeletal events may occur more rarely. To avoid these complications, an adequate assessment and risk stratification is carried out before starting the training program. The training you will carry out will be below your initial capacity, you will be taught the correct breathing maneuvers and training techniques and the necessary measures will be taken for your safety. If necessary, oxygen will be added during the breathing exercises.

Confidentiality

If you agree to participate in this study, you must be aware that some information about your health will be used and incorporated into a computerized database without your personal data. All data will be kept confidential and only your doctor will know your identity. The information will be protected under the protection of the data protection law 15/1999 of December 13, being able to exercise the rights of access, modification, opposition and cancellation of data if required, having to contact the doctor responsible for the study for this.

Who do I contact if I have more questions throughout the study

If you have any questions or clarification regarding the study, or if you need help for any health problem related to this project, you can contact the research doctor: Dr. Sindy Cedeño or Dr. Almadana. Contact telephone number 600 16 22 52.

Clinical history number Age Birthdate

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PATIENT STATEMENT
Mr./Mrs.....Date of birth…….
National identity document……Age.....

Mr./Mrs.....
Address.....
As a legal representative, family member or close friend, with national identity document .....

That Dr..... .....he explained to me that What does the **home rehabilitation program** consist of, the benefits and possible adverse events.

And that I have understood the meaning of the treatment and the risks inherent to it and I declare that I am duly informed as provided in articles 8, 9 and 10 of Law 41/2002 of November 14, basic regulation of patient autonomy and the rights and obligations regarding information and clinical documentation, having had the opportunity to clarify my doubts. I have also received an answer to all my questions, having made the decision freely and voluntarily

Mr ./ Mrs…….
Dr ./ Dr. (Name, Surname, Collegiate number)
……..……..

I know that the signing and granting of this informed consent do not imply any waiver of possible future claims, both medically and legally. I also know that I can withdraw from signing this consent at any time prior to the intervention.

REVOCATION OF CONSENT

I revoke the consent given on the date ..... of ..... of 2 0..... and I do not wish to continue with respiratory rehabilitation. Reflect date:

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The Physician The patient

The team that develops this of pulmonary rehabilitation home based program ensures the promotion and protection of health and to guarantee the safety of people. If you have any questions, you can contact the research team's doctor/rehabilitator/physiotherapist. Contact telephone number 600 16 22 52/ 667 39 26 45