PATIENT INFORMATION

Please read the following information carefully and ask any questions you may have before signing this informed consent.

Background:

Sleep apnea hypopnea is a significant public health problem in which the airway repetitively closes during sleep. It is associated with snoring, sleep fragmentation, excessive daytime sleepiness and increased cardiovascular risk. There are multiple causes of sleep apnea, and these can include anatomical and physiological factors. The upper airway dilator muscles are crucial for the maintenance of pharyngeal patency and may contribute to the incidence of this disease.

What is the objective/importance of this study?

To study the influence of performing a set of oropharyngeal exercises, known as 'myofunctional therapy', in the progression of patients diagnosed with sleep apnea hypopnea. These exercises are derived from speech therapy and involve exercises using the tongue, soft palate and pharyngeal wall, including sucking, swallowing, chewing, breathing and speaking.

Tongue and oropharynx exercises (myofunctional therapy) may be an attractive alternative treatment for snoring and sleep apnea to improve the quality of life of patients who suffer from this disorder. The problem is that it is currently not known which patients are most suited for this treatment.

Why have you been asked to participate?

You've been asked to participate in this study as you have been diagnosed with sleep apnea, meaning your breathing stops and starts during sleep.

What will your participation involve? What kinds of tests or procedures will you undergo?

Your participation in this study will involve undergoing a functional examnation of your oropharyngeal muscles and you will be asked to complete a series of questionnaires. Measurements will also be taken of the strength of your tongue, your orbicular muscles, as well as your height, weight, BMI and neck and abdominal circumferences. We also do a ultraound measurement of the fat of your tongue.These would be carried out in a single visit to the centre. There were three groups and oropharyngeal exercises will be performed in two and shame therapy. Asignament will be blind and therapy will last 3 months. Afterwards measurements will be again taken.

What are the general risks of participating in this study?

So far there have been no complications resulting from this procedure. No additional risk is foreseen for you.

What are the benefits of participating in this study?

To improve the selection of patients who may benefit from myofunctional therapy.

It is highly likely that the results obtained from this study will help to better understand your disease and improve the prognosis and treatment of future patients.

What will happen if I choose to not take part in this study?

Your participation in this study is completely voluntary. In the event that you decide not to participate in the study, this will not affect the treatment and monitoring of your illness by your doctor or the rest of the health personnel who treat your sleep apnea. Likewise, you can withdraw from the study at any time, without having to give a reason.

Who can I contact if I have any questions?

It is important you raise any questions or concerns you may have with the project researchers before signing the consent form. Likewise, you can ask for additional information about the study and what will happen throughout it by contacting the main project researcher, Dr Carlos O Connor (658059669) or by email coconnor@us.es, or the pneumology service via telephone 645 802 433 or email pulmonología.hmb@quiron.es

Confidentiality:

All your data, as well as all medical information related to your illness, will be treated with absolute confidentiality by the personnel in charge of the research. Likewise, if the results of the study are published in scientific journals, the personal data of the patients who took part in the project will not be shared at any point.

As provided by Organic Law 15/1999 on the Protection of Personal Data, you may exercise your right to access, rectify and delete your data by contacting the main project researcher.

Patient involvement:

- Participation is completely voluntary.
- The patient can withdraw from the study at any time, without giving a reason and without this affecting their medical care.
- All personal data obtained from this study is confidential and will be treated in accordance with the Organic Law on the Protection of Personal Data 15/99.
- The information obtained will be used exclusively for the specific purposes of this study.