Date : 10.6.2016

The Effect of a Combined Home-based Orofacial Exercise Program on Oral Aperture of Patients With Systemic Sclerosis: a Single-blind Prospective Randomized Controlled Trial

NCT number: 04336475

Informed Consent Form

You are being invited to take part in a research study (also known as clinical trial), named the effect of a combined Home-based Orofacial Exercise Program on Oral Aperture of Patients With Systemic Sclerosis: a Single-blind Prospective Randomized Controlled Trial'.

Systemic sclerosis is a chronic disease that can both involve skin and internal organs. The skin involvement can be as thickening of the skin. Patients with skin involvement are divided into diffuse and limited skleroderma. In diffuse scleroderma skin involvement includes arms, legs and trunk regions. In limited scleroderma skin thickening is not seen above elbows and knees. In both types face involvement can be seen. The involvement of face can result in difficulty in opening mouth, chewing and maintaining oral hygiene. This situation can lead to nutritional disorders and psychological stress in patients. Some massage and exercise techniques that have been shown to be beneficial for the mouth opening have been reported.

In this study, the effectiveness of the exercise program will be evaluated in patients with facial involvement that decrease the mouth opening of the scleroderma. Patients who agree to participate in the study will be randomly divided into two groups. Oral aperture measurements, chewing muscles examinations and oral hygiene evaluations of all patients will be made by a dentist. Both groups will be informed about scleroderma and oral hygiene techniques, and a training and exercise program will be provided to increase mouth opening to all patients. Patients who will join the first group will perform exercise program in the first month with oral hygiene care, and the second month will continue with only oral hygiene care. The second group will pay attention only to oral hygiene care in the first month and they will perform the exercise program in the second month. Exercise program and related equipment will be given to patients in the form of paper printouts with illustrations and explanations. Mouth opening measurements of both groups will be done by the dentist before, at the end of the at first month and at the end of the second month after treatment. Researchers, care givers, ethics committee members, institutional and other relevant health authorities may have direct access to the volunteer's original medical records, but this information will be kept confidential. By signing the written informed volunteer consent form, the volunteer or his legal representative will grant such access. In accordance with the relevant legislation, the records that will reveal the identity of the volunteer will be kept confidential and will not be made public; even if the results of the research are published, the identity of the volunteer will remain confidential.

Participation in our research is entirely voluntary and participation has no material return. Participation of the volunteer in the research is voluntary and the volunteer may refuse to participate in the research or withdraw from the research at any time, without any penalty or sanction, without losing any right. The volunteer or his legal representative will be informed in a timely manner when new information regarding the research subject is available, which may affect the volunteer's willingness to continue to participate in the research.

I have read all the comments on the Informed Consent Form. The written and verbal explanation to me about the research mentioned above and its purpose was made by the doctor named below. I know that I voluntarily participated in the research, I can leave the research with or without reason. I agree to participate in this research with my own consent, without any pressure or coercion.

Date:

Patient's Name-Surname: Patient's Signature:

Name and surname of the doctor who made the explanations: Signature:

Witness : Name-Surname: Signature: