

**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

## **Study Protocol**

The study was designed as a single-blind, prospective, randomized controlled study with a 2-month follow-up period, carried out in rheumatology outpatient clinic, between March 2017 - January 2019. SSc patients who fulfilled the *American College of Rheumatology* (ACR) 2013 criteria with an OA of <40 mm were included in the study. All patients were previously undergone dental examination by a dentist to exclude oral manifestations and dysfunction of temporomandibular joint that may interfere with attempts to exercise. Patients with missing teeth, dysfunction of temporomandibular joints, oral malignancy, recent dental procedures, multiple active digital ulcers and diagnosed psychiatric conditions were excluded. The study has been approved by the local ethical committee (10.06.2016; protocol number:54) and the written informed consent was taken from all the patients included in the study.

Patients' sociodemographic properties were recorded at the first visit. Disease duration was calculated from the first manifestation of the disease. The severity of the disease was evaluated by Medsger's disease severity scale. Patients were randomly divided into two groups. Randomization was done as the sealed envelope method. After the informed consent was taken, the opaque envelope that the patient have chosen was opened and patients were offered the allocated treatment regimen. Group 1 was given exercise regimen and oral hygiene care advices for the first one month; followed by no exercise but oral hygiene care advices for the next four weeks. Group 2 received oral hygiene care advices for the first one month, followed by the exercise regimen twice a day along with oral hygiene care advices for the next four weeks . Oral care advices were given to every participant by a dentist involved in the study at their first visit. The reason of this design aims to increase the sample size to be analyzed receiving exercise treatment, since scleroderma caused microstomia is a rare condition. The exercise program was demonstrated to patients by a clinician at the first visit and given to all patients printed as a manual to be done every day for one month duration of the exercise program. Additionally, a diary was given to patients to mark when they have completed the exercise and to note in the case of pain on daily basis. The exercise regimen was developed on the basis of previous studies and clinical knowledge.

Patients' OA was measured at baseline, 1-month, and 2-months by an experienced dentist at the faculty of dentistry. All the measurements were done by the same dentist who is blind to the exercise regimens to provide consistency. The OA was measured using the interincisal distance between the maxillary and mandibular central incisors in the midline. Patients were asked to open their mouth as wide as they could in the natural head position. The linear distance from the incisal edge of the upper central incisor to the incisal edge of the lower central incisor was recorded using a dental bow compass and measured using a millimeter ruler. Each subject was measured three times every two minutes and the highest value of these three measurements was recorded.

#### *Statistical analysis*

The IBM SPSS Statistics version 20.0 software package was used for analysis. Categorical variables are expressed as numbers and percentages, whereas continuous variables are summarized as mean and standard deviation and as median and minimum- maximum where appropriate. To compare categorical variables between the groups the chi-square test was used. The Shapiro-Wilk test was used to confirm the normality of distribution for continuous variables. For the comparison of continuous variables between two groups, the Student t test or Mann-Whitney U test was used depending on whether the statistical hypotheses were fulfilled. To evaluate the change in OA measurements obtained in the time interval and to compare the trend in OA measurements between groups, the Repeated Measurements Analysis was applied. The level of  $p<0.05$  was considered as statistically significant.