

CLINICAL STUDY PLAN

The Effects of Neuromuscular Electrical Stimulation on Swallowing Functions in Stroke Patients With Dysphagia

INFORMED CONSENT FORM

I-INFORMATION OF THE RESEARCH

STUDY NAME: The Effects of Neuromuscular Electrical Stimulation on Swallowing Functions in Stroke Patients With Dysphagia: Randomized Controlled Trial

RESEARCH INSTITUTE : Istanbul University, Istanbul Faculty of Medicine, Department of Physical Medicine and Rehabilitation

THE AIM OF THE STUDY:

By definition, dysphagia refers to the difficulty in the transition of food from the mouth to the stomach. Post-stroke dysphagia is the most common cause of difficulty in swallowing caused by a loss of coordination or loss of strength of the muscles that advance the food from the mouth to the stomach. Dysphagia is a common problem affecting approximately 78% of stroke patients. In 11-50% of patients, difficulty in swallowing persists in the 6th month after stroke.

It is recommended to all patients to determine whether there is difficulty swallowing by means of instrument evaluation and to repeat the evaluation after treatment. Instrumental evaluation according to the swallowing assessment made at the bedside; It is more advantageous in showing dysphagia and predicting complications that may occur.

When there is difficulty in swallowing in the patient; Complications such as prolonged hospital stay, delay in the rehabilitation process, weight loss, water loss in the body, increased risk of infection, increased risk of pneumonia, and death can be observed. Swallowing rehabilitation is of great importance in the prevention of these complications.

Purpose in swallowing rehabilitation; performing safe oral nutrition, ensuring adequate nutrition and water intake, and preventing complications such as food leakage into the trachea. Traditional swallowing rehabilitation program; Includes diet and nutrition training, posture changes, and assistive techniques such as different swallowing maneuvers, exercises to improve the function of the muscles that help swallow and control the food, joint range of motion exercises to protect

the airway, exercises to open the upper esophageal sphincter (facilitate the transition from the esophagus to the stomach).

Neuromuscular electrical stimulation (NMES) is the use of low-level electrical current to create muscle contraction. In the field of Physical Therapy and Rehabilitation, NMES is used in case of neurological injury resulting in muscle weakness. NMES is used for weakness in muscles that provide post-stroke swallowing function. NMES significantly speeds up swallowing function recovery in patients with stroke swallowing.

In this thesis, it is aimed to investigate the effectiveness of neuromuscular electrical stimulation on functional status, swallowing effectiveness, physical condition and quality of life, as well as diet and nutrition education, protection and exercise programs in patients with post-stroke dysphagia.

With this clinical study you will participate; You will have been treated appropriately for dysphagia after stroke, learned the training and exercise program, and also contributed to the provision of scientific data on the effects of treatment.

STUDYING TECHNIQUE AND CONTENT OF THE STUDY:

Patients who have registered between the dates of 15 April 2020 and 15 October 2020 in the Neurological Rehabilitation Unit of Istanbul University Istanbul Medical Faculty, Department of Physical Medicine and Rehabilitation will be included in the study.

The study was planned to cover a total of 38 patients. Patients will be divided into two groups according to the order of application. Traditional dysphagia (swallowing disorder) treatment (TDT) program will be applied to both groups. TDT program; diet and nutrition training includes teaching the body and head posture techniques during nutrition, mouth and tongue exercises, swallowing training, esophagus-feeding exercises, and chin-pushing exercise. resistance. The TDT program will be held with a doctor for 45 minutes a day, 5 days a week, and for 3 weeks. After the exercise program, a group will receive neuromuscular electrical stimulation for 45 minutes in addition to these treatments. It will be applied by connecting two electrodes to both sides of the neuromuscular electrical stimulation area, which is one of the physical therapy methods under the chin/neck. The purpose of this method is to strengthen these muscles by vibrating the muscles that provide swallowing in the chin/neck area.

If you want to participate in this research study, you will be asked to sign this approval form with a date. The screening will be done to determine your eligibility without being included in the study. Your demographic information, such as your name, surname, age, gender, stroke characteristics, and swallowing assessment, as with all patients included in the study, will be recorded during this evaluation. The study period is about 6 months and some evaluations will be made before, after treatment, and at the third-month control. Initially, after the treatment and at the 3rd-month control, your functional nutritional grade will be evaluated, and the degree of your swallowing difficulty will be evaluated with questionnaires that will fill the effects of your swallowing difficulty on your general condition and quality of life. These followups are routine examinations at the neurological rehabilitation outpatient clinic and do not harm you and you will not be charged any additional fees. The second part of the evaluation at the beginning and after the treatment will be done in the Otorhinolaryngology Clinic. In this section, you will be asked several questions before you can question your voice complaints. If you accept later, a thin camera will be sent through your nose first, and while this camera is on your nose, you will be asked to drink a larger amount of water, first with a small amount of water, and then food coloring. After drinking the water, while the camera is still in your nose, yogurt and then 1 biscuit will be given. You may feel pain while passing the camera through your nose while doing this test, cotton can be put on your nose to prevent this. Similarly, as the camera moves through your nose, your blood pressure may drop or you may feel pain when the camera moves into your mouth. If you encounter such a problem, the test will be terminated. Apart from these, you are not expected to encounter any other problems during the swallowing test. After the swallowing test, your vocal cord examination will be done. During this examination, your tongue will be held with a cloth and a camera will be placed up to the entrance of your throat. While the camera is in your throat, you will be asked to make various sounds. The only risk that may arise during this examination is gagging. If you grind, you can anesthetize your throat with a spray or stop the examination at any point. The swallowing test will take about 10 minutes, and the vocal cord examination will take about 5 minutes.

In case of an unexpected situation that occurs after inclusion in the study, the patient can be excluded from the study with the knowledge of the doctor. If you are involved in the study, you should not participate in another treatment program that affects your swallowing during the treatment program without the knowledge of the doctors planning to study. All patients included in the study will be informed about prevention and treatment. As a volunteer participating in a

research study, you have certain responsibilities that you need to fulfill, such as filling out job-related forms correctly and following your follow-up on time and implementing your home exercise and protection program.

II- INFORMATION ABOUT THE RIGHTS OF THE VOLUNTEER:

In the treatment of post-stroke dysphagia, diet and nutrition education, protection, exercise programs, as well as neuromuscular electrical stimulation therapy are the main treatment methods. Diet and nutrition education, protection, exercise programs will be applied to the patients included in both groups in our study, and some patients will receive neuromuscular electrical stimulation in addition to these treatments. During the study and after the study, if you do not benefit from the treatment methods applied, your treatment will be completed by applying different treatment options.

Your participation in this study is voluntary, and if you decide not to participate, you will not suffer any harm or the benefits you will see outside of this study will not be lost. You have the right to refuse to participate. In addition, you can withdraw from the study by informing the researchers at any time or you can be excluded from the research when deemed necessary by the researchers. You will not be liable for any monetary responsibility for the expenditures for the research, and you will not be paid. The personal information that will be taken from you will be used only in the mentioned work and your credentials will be kept confidential.

PARTICIPANT DECLARATION

The above information about this research was conveyed to me by Dear Doctor stating that medical research will be carried out within the Department of Physical Medicine and Rehabilitation, Istanbul University Istanbul Medical Faculty. After this information, I was invited to such research as a "participant" (subject). If I participate in this research, I believe that the confidentiality of the information that I should stay with the physician will be approached with great care and respect during this research. I was given sufficient confidence that my personal information will be protected with the utmost care during the use of research results for educational and scientific purposes.

I can withdraw from the research without showing any reason during the execution of the project. (However, I am aware that it would be appropriate for me to foresee that I will withdraw from

the research in order not to leave the researchers in a difficult situation.) I can also be excluded from the research by the researcher, provided that my medical condition is not harmed.

I do not assume any monetary responsibility for the expenditures for the research. I will not receive a payment.

Necessary assurance was provided that any medical intervention would be provided if any health problems that may arise from the research application, whether direct or indirect, occur. (I will not be under a monetary burden with these medical interventions as well). When I encounter a health problem during the research; at any time, I know that I can call Doctor from the numbers +902124142000-31737 and from the Istanbul Faculty of Medicine, Department of Physical Medicine and Rehabilitation Fatih / Istanbul.

I do not have to participate in this research and may not participate. I have not encountered compelling behavior in participating in the research. I also know that if I refuse to participate, this will not harm my medical care and my relationship with the physician. I have understood all the explanations made to me in detail. I decided to take part in this research project mentioned as a “participant” (subject) at the end of a certain thinking period on my own. I accept the invitation to this matter with great satisfaction and volunteerism. A copy of this signed form sheet will be given to me.

INFORMED CONSENT SIGNATURE PAGE

I have read the text above, which shows the information to be given to the volunteer before research. I have been given written and verbal explanations about these. Under these circumstances, I agree to participate in this clinical trial with my own consent, without any pressure or coercion.

Date:

Volunteer;

Name and surname:

Signature:

Address:

Phone number:

The researcher who made the explanations;

Name and surname:

Signature:

The institution officer who witnessed the consent process from the beginning to the end;

Name and surname:

Role:

Signature: