**Official Title:** Effectiveness of Transcranial Magnetic Stimulation on Dysphagia in Patients with Parkinson's Disease: A Randomized Double-Blind Study

**Unique Protocol Id: E-70198063**

**Date: 22.10.2025**

**INFORMED CONSENT FORM**

1. Name of the study:

Effectiveness of Transcranial Magnetic Stimulation Treatment in Dysphagia Developing in Patients Diagnosed with Parkinson's Disease: A Randomized Double-Blind Study

2. Purpose of the Study:

This study is being conducted for clinical research purposes within the Department of Physical Medicine and Rehabilitation at Ege University Hospital. The main objective of this study is to compare the effectiveness of rTMS (repetitive Transcranial Magnetic Stimulation) applied at different frequencies in the treatment of dysphagia developing in patients diagnosed with Parkinson's disease.

3. Study Method:

The volunteer is expected to continue the study for a total of 9 months, with a 2-week treatment period and a control swallowing test at the 9th month. A total of 26 volunteers are planned to be included in the study.

During the study, various questionnaires lasting approximately 15 minutes will be administered to patients three times: before treatment, after treatment, and at the 9-month follow-up.

During the study, a magnetic field will be applied to the area of the brain that controls the swallowing muscles using an rTMS device.

Treatment will consist of a total of 10 sessions at 5 sessions/week. Each session will last an average of 45 minutes. In addition to rTMS treatment, volunteers will be asked to perform swallowing exercises regularly. Volunteers will be divided into two groups and treated at two different frequencies, 5 Hz for one group and 10 Hz for the other. Volunteers will be randomly assigned to groups.

4. Possible Side Effects:

Common side effects of the treatment include headaches, facial muscle spasms and twitching; very rarely, seizures and emotional fluctuations may occur, especially in individuals with a history of bipolar personality disorder.

5. Other Treatment Options:

In addition to the rTMS device used in our study to treat swallowing disorders associated with Parkinson's disease, NMES (neuromuscular electrical stimulation) and PMS (peripheral magnetic stimulation) may also be administered to volunteers. Skin sensitivity and redness are

common side effects of NMES treatment. PMS treatment cannot be administered to patients with metal implants, hearing aids, or epilepsy in the body region receiving treatment.

6. Withdrawal from the Study:

Participation in the study is voluntary, and the volunteer may refuse to participate in the study or withdraw from it at any time without penalty or coercion and without losing any rights.

7. Ensuring Confidentiality:

The volunteers' names, surnames, ages, genders, locations, telephone numbers, and personal data regarding additional illnesses will be processed.

Records that could reveal the volunteer's identity will be kept confidential and will not be disclosed to the public; even if the research results are published, the volunteer's identity will remain confidential.

Observers, screeners, the ethics committee, the institution, and other relevant health authorities will have direct access to the volunteer's original medical records, but this information will be kept confidential. By signing the written informed consent form, the volunteer or their legal representative will have consented to such access.

8. Measures and warnings for volunteer safety:

When new information related to the research topic is obtained that may affect the volunteer's willingness to continue participating in the research, the volunteer or their legal representative will be informed in a timely manner.

After treatment, volunteers are expected to show improvement in their swallowing function based on the results of the questionnaires and swallowing tests conducted. However, if there is no targeted clinical benefit for the volunteer, they will be informed of this situation.

Volunteers can contact Dr. Kübra Efe at "0552 351 00 52" for more information about the research, their rights, or any side effects related to the research.

If the volunteer is scheduled to have a brain pacemaker implanted due to Parkinson's disease during the treatment period, they will need to be excluded from the study if they experience a seizure during treatment.

9. What is Expected of Volunteers:

Volunteers are expected to continue participating in the study and adhere to the schedule for the control swallowing test.

10. Storage of Biological Samples:

No biological material will be collected from volunteers.

11. Research/Volunteer Documents:

A copy of the informed consent form will be provided to the volunteer.

I have read all the explanations in the informed consent form. The physician named below provided me with written and verbal explanations regarding the research described above. I understand that I am participating in this research voluntarily and that I may withdraw from the research at any time, with or without cause. Within the scope of the clinical research at hand, I give my EXPRESS CONSENT to the collection and processing of my personal data, its sharing as specified in the consent form, its use in scientific studies after being anonymized, and its transfer abroad. I agree to participate in the research in question of my own free will, without any pressure or coercion.