12/07/2024

Informed Consent Form

Title of Study: Improvement of Pelvic Floor Function Using Repetitive Transcranial Magnetic Stimulation and Posterior Tibial Nerve Stimulation in Treating Neurogenic Overactive Bladder in Patients With Multiple Sclerosis

Principal Investigator: Elena Fernández Espinar

Introduction: You are invited to participate in a research study. Before you decide whether or not to participate, it is important that you understand why the research is being conducted and what it will involve. Please read the following information carefully and feel free to ask any questions you may have.

Purpose of the Study: The purpose of this study is to evaluate and compare the efficacy of repetititve transcranial magnetic stimulation (rTMS) versus Percutaneous Tibial Nerve Stimulation treatment (PTNS) in managing overactive neurogenic bladder in Multiple Sclerosis (MS) patients under follow-up at Hospital Universitario de la Princesa.

Procedures: If you agree to participate in this study, you will be asked to undergo the following procedures:

- You will be randomly assigned to receive either the rTMS treatment combined with /or PTNS. Three groups of participants will be created for the study: One group will receive treatment with rTMS and PTNS, the second group will receive only rTMS, and the third group will receive PTNS as treatment.
- The treatment sessions will occur three times a week for a duration of 3 weeks.
- Each session will last approximately 30 minutes.
- You will be asked to complete several questionnaires and assessments throughout the study period to evaluate your symptoms and overall well-being.

Risks and Benefits

Risks of rTMS: Participation in this study involves some risks with recovery typically occurring withing a few days, including:

- Headache
- Paresthesia or pain in limbs
- Restless legs sensation
- Increased bladder spasticity
- General discomfort

Risks of PTNS: Some adverse events that may occur and could be associated with this technique include:

- Skin irritation
- Temporary increase in pain or discomfort at the stimulation site during the application of electrical current
- Rare cases of skin lesions
- Very rare cases of allergic reactions and/or general discomfort

You are responsible for reporting any occurrence of the aforementioned adverse events. Management of these events will be conducted following current safety standards for the techniques used.

Benefits of rTMS:

- Symptom Relief: Potential reduction in neurogenic overactive bladder symptoms, improving urinary control.
- Non-Invasive: A non-surgical treatment option with minimal recovery time.
- Improved Quality of Life: Enhanced daily functioning and quality of life due to better bladder control.
- Adjunctive Therapy: Can be used in conjunction with other treatments to maximize therapeutic effects.

Benefit of PTNS:

- Symptom Improvement: Potential reduction in bladder overactivity and improvement in urinary symptoms.
- Minimally Invasive: A less invasive alternative to surgical interventions.
- Outpatient Procedure: Conducted in an outpatient setting with no need for hospitalization.
- Low Risk: Generally well-tolerated with a low risk of serious side effects.
- Complementary Therapy: Can be combined with other treatments for enhanced benefits.

By participating in this clinical trial, you contribute to advancing medical research, potentially benefiting future patients with similar conditions. It is important to weigh these risks and benefits carefully. Please discuss any concerns or questions with your healthcare provider before consenting to participate in this trial.

Confidentiality

Your privacy is very important to us. All information collected during this study will be kept confidential. Your data will be coded and stored securely, and only authorized personnel will have access to it.

Voluntary Participation

Your participation in this study is entirely voluntary. You may choose not to participate or to withdraw from the study at any time without any penalty or loss of benefits to which you are otherwise entitled.

Contact Information

If you have any questions about this study, please contact:

Name: Elena Fernández Espinar

Telephone number: +34915202200 ext 19501

E-mail: efespinar@salud.madrid.org

Consent

STATEMENTS AND SIGNATURES

PATIENT OR LEGAL GUARDIAN/RELATIVE

I have read and understood the information provided above. I have had the opportunity to ask questions, and all my questions have been answered to my satisfaction. I agree to participate in this study.

I may withdraw my consent at any time

As: PATIENT LEGAL GUARDIAN OR RELATIVE

Signed:

Date: ----------

PRINCIPAL INVESTIGATOR

I have informed this participant and/or legal representative of the purpose and nature of the procedure described as well as its risks and alternatives.

Signed:

Date: ----------