GENERAL STUDY INFORMATION AND INFORMED CONSENT

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dr. Sergio Montero Navarro

TITLE: Second-generation Radiofrequency Application and Specific Therapeutic Exercise as a Treatment for Stress Urinary Incontinence Due to Urethral Instability. Randomised Clinical Trial

Research and Ethics Committee of CARDENAL HERRERA CEU UNIVERSITY: CEEI25/646

NCT ID:

DATE: 01-14-2026

GENERAL STUDY INFORMATION

TITLE: **Second-generation Radiofrequency Application and Specific Therapeutic Exercise as a Treatment for Stress Urinary Incontinence Due to Urethral Instability. Randomised Clinical Trial**

Mr. Sergio Montero Navarro, Physiotherapist, principal investigator and researcher reports that:

The tests performed are simple and in no case involve difficulty, fatigue, danger, injury, pain or adverse reaction.

They will be carried out by collegiate physiotherapists in the School of Physiotherapists of the Valencian Community.

The general data of the subject will be collected (name, age, sex, physical variables and clinical history). The article must be sent with comfortable clothes The day that sea cited by the researcher, previous notice. Personal data is recognized in this study.

The personal data are confidential, apply to the protection of personal data (Organic Law 15/1999, December 13) and any other thing that may be applicable.

This study was approved by the Research and Ethics Committee of CARDENAL HERRERA CEU UNIVERSITY: CEEI25/646

INFORMED CONSENT

Mr/Mrs .....with Number identification .....freely and voluntarily, I DECLARE:

That I have read the information contained in this document about the general information of the study.

I have been informed that all tests are simple to perform and do not produce harmful effects on health. They will be carried out in appropriate facilities and will be carried out by qualified and specialized personnel.

I have also been informed that, the data collected in this study will be treated confidentially, applying the current legislation on protection of personal data (Organic Law 15/1999, of December 13) and any other applicable.

Therefore, I give my consent and I authorize Mr. Sergio Montero Navarro, to carry out the detailed study in this document with the help of the necessary personnel with the appropriate qualification and specialization.

In Elche, to ..... of.....of 202

SIGNED:

STUDY PROTOCOL PLAN AND STADISTICAL ANALYSIS PLAN (SAP)

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STUDY PROTOCOL PLAN

Objectives:

The objectives of our study have been the following:

The purpose of this study is to evaluate the correlation between urethral instability, assessed by ultrasound analysis of the bladder neck opening, and the severity of SUI, assessed by validated standard questionnaires. The determination of standard ultrasound parameters that allow urethral instability to be related to the severity of SUI would be a valuable finding for accurately diagnosing the severity of SUI using low-cost, easy-to-use imaging methods.

A randomized, single-blind clinical trial will be conducted in women with stress urinary incontinence (SUI). Participants will be randomly assigned to one of three intervention groups: radiofrequency (RF), specific pelvic floor muscle exercise (PFMT), or combined treatment (RF + PFMT). The study will be carried out at Clínica Traña (San José, Costa Rica), with an expected start date in 2025. The study will adhere to the principles of the Declaration of Helsinki and current European data protection regulations.

Adult women with urinary leakage and a bladder neck opening greater than 90°, assessed by functional ultrasound, will be included. Women with other pelvic floor disorders, pregnancy, recent treatments (RF, PFME, hormonal or laser therapies), relevant neurological, metabolic, or cardiovascular conditions, prior pelvic surgery, active infections, or contraindications to the interventions will be excluded. The estimated sample size is 117 participants (39 per group), calculated to detect statistically significant differences with 80% power and a 5% significance level, allowing for a 30% dropout rate.

Before the intervention, all participants will undergo physical examination, digital palpation, and functional pelvic floor ultrasound, as well as complete validated questionnaires assessing urinary incontinence severity and quality of life (ICIQ-SF, King's Health Questionnaire, and Sandvik Severity Index). These assessments will be repeated at the end of the intervention and at 15 days, 3 months, 6 months, and 12 months post-intervention.

Randomization will be performed using statistical software, and outcome assessors will remain blinded to group allocation. Data will be coded and securely stored, ensuring participant confidentiality in accordance with the General Data Protection Regulation (EU 2016/679).

The RF intervention will consist of five weekly sessions of non-ablative fractional vaginal radiofrequency with temperature control and standardized parameters. The PFME program will comprise a structured core and pelvic floor exercise protocol supervised by physiotherapists, conducted twice weekly over a 16-week period. The combined group will receive both interventions.

Primary outcomes will include pelvic floor muscle strength and function (Oxford scale, endurance, and fatigability), ultrasound parameters (bladder neck opening, urethral hypermobility, and presence of prolapse), and validated questionnaires assessing urinary incontinence severity and quality of life.


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Statistical Analysis Plan (SAP)

Data will be expressed as mean ± standard deviation or as a percentage. The distribution of the sample will be determined using the Kolmogorov-Smirnov test. For quantitative variables, depending on the type of variable, Student's t-test or Mann-Whitney U test will be performed. The correlation between variables will be analyzed using Spearman's correlation. In the case of qualitative variables, the association between variables will be analyzed using bivariate or multivariate logistic regression, as appropriate, and contingency tables. The statistical significance of the difference between them will be evaluated using Pearson's $\chi 2$ test. Statistical significance will be assumed with p-values <0.05.

To evaluate the diagnostic capacity of bladder neck opening measured by ultrasound analysis in the classification of the severity of stress urinary incontinence, a logistic regression analysis was performed. The dichotomized severity of the Sandvick test (mild/moderate versus severe/very severe) will be taken as the gold standard. Demographic and clinical variables will be evaluated as possible covariates and included in subsequent models if they had a p-value < 0.200.

Sensitivity, specificity, Youden's index (sensitivity + specificity − 1), and positive and negative likelihood ratios (LR+ and LR−) will be calculated for bladder neck opening at rest, during the Vasalva maneuver, the variation between the two, and for the maximum model with the three variables.

The optimal cutoff point for bladder neck opening at rest will be determined using the Youden index. Subsequently, this value will be transformed into clinical units (mm) by algebraic solving of the logistic model equation, adjusted for relevant covariates (age and BMI). This approach preserves the statistical fit of the model while providing a clinically interpretable threshold.

Studentized residuals, leverage values, and Cook's distances will be estimated to identify possible outliers and influential values in the dependent variable, the predictors, and the model as a whole.

Receiver operating characteristic (ROC) curves will be constructed to determine the area under the curve (AUC). Likewise, the Hosmer-Lemeshow goodness-of-fit test will be applied to compare the observed and expected frequencies of the model (considering $p > 0.05$ as an adequate fit). The accuracy of the probabilistic predictions will be evaluated using the Brier Score (lower values indicate better performance). The

analysis will be performed using SPSS Statistics 29.0 (IBM Corp.)