Title of the research study:

Effects of ultrasound-guided percutaneous neuromodulation of the accessory nerve and specific neck exercises in patients with whiplash injury in the subacute period: a randomised clinical trial.

Authorization of study: June 14 2025

1. Objective(s):

Primary objective

To investigate whether adding a session of NMP-e on the accessory nerve to a treatment based on specific neck exercises achieves additional improvement in the degree of disability in patients with whiplash in the subacute phase.

Secondary objective

To investigate whether adding an NMP-e session on the accessory nerve to a treatment based on specific neck exercises achieves additional improvement in active cervical range of motion (ROM), pain intensity, and pressure pain thresholds in the trapezius muscles in patients with whiplash in the subacute phase.

1.1. Benefits of the study:

- To investigate the efficacy and safety of NMP-E of the accessory nerve in patients with whiplash.

- To contribute to improving the quality of life of patients with whiplash through new therapeutic proposals.

- Generate solid scientific evidence for NMP-E treatment of the accessory nerve in the management of whiplash in the subacute phase.

- Optimise rehabilitation resources by proposing more effective and cost-effective interventions.

- At the individual level, participants included in the study will receive free physiotherapy treatment aimed at improving their symptoms.

2. Type of research

Randomised controlled clinical trial with parallel groups and blinded evaluator.

3. Materials and Methods:

3.1. Study population.

Subjects: Adult patients of both sexes diagnosed with whiplash injury in the subacute phase, at least two weeks after the injury occurred. The study will be conducted at the VIAMED Los Manzanos Hospital in Logroño. Patients will be recruited through the physician responsible for their assessment and diagnosis. Participants will be informed of the objectives and procedures of the study and will sign an informed consent form prior to their inclusion.

Inclusion criteria:

· Having suffered a traffic accident within a period not exceeding 2 weeks prior to the evaluation.

· Diagnosed with Grade I or II Whiplash Associated Disorder (WAD) according to the Quebec Task Force (QTF).

· Be at least 18 years of age.

· Have a Visual Analogue Scale (VAS) score greater than 20 mm.

· Have a cervical disability greater than 1 point according to the Cervical Disability Index (NDI)

Exclusion criteria:

· Neck pain resulting from previous traffic accidents

· Conditions that may interfere with full participation (cardiovascular and neurological diseases and severe mental disorders)

· Pharmacological and/or physiotherapy treatment prior to starting the study

· Cervical surgery and congenital spinal disorders

· Fractures and/or dislocations of the cervical vertebrae

· Alcohol or drug abuse

· Allergies to metals

· Belonephobia

3.2. Sample size:

It is estimated that a total of 44 patients will need to participate in this parallel-design study with two treatment arms. The sample size was calculated based on an 80% statistical power for the study to detect a difference between treatments and a two-tailed significance level of 0.05. The difference to be detected is 10.4 points in the primary NDI variable, taking into account that the

standard deviation of this variable in populations similar to the study population is 11.9. (4)

3.3. Methodology:

Study design A randomised controlled clinical trial with parallel groups and a blinded evaluator will be conducted. The study will evaluate the effects of e-PMS of the accessory nerve combined with specific neck exercises in patients with whiplash injury in the subacute period.

Variables

Primary variable:

Cervical disability measured with the NDI questionnaire.(2)

Secondary variables:

Pressure pain thresholds in the ascending fibres of the trapezius muscle using pressure algometry.

Active cervical range of motion (ROM) measured with a conventional goniometer.

Average pain intensity in the last week measured with VAS (0-10).

Procedure

Patients will be randomly assigned to each study group, as the centre's administration will have a closed box with ballots numbered from 1 to 60. The patient will take a ballot, and if it is in the range [1,30], they will be assigned to the control group, and if it is in the range [31,60], they will be assigned to the experimental group. The slips of paper they draw will be given to the researcher in charge of administering the intervention.

Groups:

Experimental group: Will receive one weekly session of e-PMS (1) of the accessory nerve combined with specific supervised neck exercises for 3 weeks. e-PNS will be performed before the exercises, using dry needling and an electrostimulator with parameters of 2 Hz to 250 microseconds for 20 minutes. The intervention on the accessory nerve will be performed on the side with the most pressure pain. This group will also receive an exercise protocol.

Control group: This group will follow the same exercise protocol as the experimental group, without receiving NMP-e treatments. (3)

The exercise protocol common to both groups will consist of two weekly sessions over 3 weeks, during which they will perform specific supervised neck exercises. The total duration of this protocol will be 40 minutes.

Assessments:

The principal investigator of the study will be responsible for conducting the assessments. Both groups will receive the same assessments.

Both groups will receive the same assessments. The assessments will be carried out before the interventions begin and there will be a total of four sessions. All study variables will be measured in the four assessment sessions. Each assessment session will last approximately 30 minutes and will take place at the following times:

- **M0 (PRE):** Before the first intervention session with NMP-e.
- **M1 (1 week post-intervention):** At the start of the second treatment session with NMP-e. week.
- **M2 (2 weeks post-intervention):** At the start of the third treatment session with NMP-e.
- **M3 (3 weeks post-intervention).** One week after completing the treatment protocol.

Handling of personal data

All participants will be pseudonymised and only the principal investigator will be aware of this pseudonymisation. This process will be carried out in an Excel document, in which the personal data of each participant will be collected and assigned a code, so that all information relating to each participant will subsequently be referenced with that identification code. This Excel document will be encrypted using the '7zip' system and the principal investigator will be responsible for its safekeeping.

The rest of the data obtained (non-personal data) will be collected in other documents, which will be headed by the participant's pseudonymisation code. Therefore, it will not be possible to associate the data with any specific participant.

3.4. Potential risks of the study:

The potential risks of the study are minor and manageable. The most significant are:

- Discomfort at the puncture site: NMP-e may cause pain or discomfort in the area where the needle is inserted

- Minor bruising or bleeding: bruising or slight swelling may appear in the treated area, as well as minimal bleeding after the needle puncture.
- Risk of infection: if proper hygiene is not followed, the puncture could cause an infection
- Temporary increase in pain or fatigue: the exercises may cause muscle fatigue or neck discomfort
- Dizziness: some movements may cause dizziness or vertigo in people with cervical problems

However, it should be noted that the probability of the aforementioned risks occurring is minimal. Firstly, because it is a procedure that has been previously validated in studies with both pathological populations and healthy subjects. Secondly, because the researcher responsible for performing the procedure has the necessary knowledge to correctly apply all hygiene and safety measures (use of sterile gloves, probe covers and skin asepsis protocols). In addition, this procedure will be performed under ultrasound guidance, which increases its safety, and will always be supervised by a professional with experience in the use of invasive physiotherapy techniques, ensuring its correct execution. The neck exercise protocol will also always be supervised by a professional.

It should also be noted that if these risks do occur, such as pain, bruising, fatigue or dizziness, they will disappear spontaneously. Other risks, such as possible bleeding, will be stopped with the use of cotton wool, although these are so minor that they would also stop spontaneously.

3.5. Statistical analysis of results and level of significance.

The statistical analysis will be performed using SPSS software. First, the normality of the quantitative variables will be assessed using the Shapiro-Wilk test. Descriptive statistics will be used to characterise the sample with the mean and standard deviation (SD) for normally distributed variables, or median and interquartile range (IQR) for non-normal variables. Frequencies and percentages will be used for categorical variables. For intragroup analysis over time, repeated measures ANOVA will be used if the assumptions of normality are met, or the Friedman test if not. For between-group analysis, Student's t-test for independent samples will be applied when normality is assumed, or the Mann-Whitney U test when normality does not exist. In addition to the significance level ($\alpha = 0.05$), the corresponding effect size will be calculated for each comparison (partial η^2 for ANOVA, Kendall's r for Friedman, Cohen's d for Student's t-test, and Mann-Whitney's r for the Mann-Whitney U test).