

Study Protocol

Official Title:

Efficacy of oxygen-ozone therapy and cervical rehabilitation on functioning in patients affected by neck pain: a prospective double-arm study

NCT Number: NCT pending

Document Date: March 20th 2026

1. Background and Rationale

Neck pain is a highly prevalent musculoskeletal condition associated with disability and reduced quality of life. Oxygen-ozone (O₂O₃) therapy has shown potential benefits in reducing pain and inflammation. However, evidence on its combined use with structured rehabilitation programs is limited. This study aims to evaluate the effectiveness of O₂O₃ therapy followed by cervical rehabilitation.

2. Study Objective

To evaluate the effectiveness of O₂O₃ therapy combined with cervical rehabilitation, and to compare McKenzie-based therapy with Back School exercises in improving pain, disability, and quality of life in patients with neck pain.

3. Study Design

Prospective, two-arm study with participants randomly allocated (1:1) to two rehabilitation groups following O₂O₃ therapy.

4. Participants

Adults (≥18 years) with chronic neck pain (≥12 weeks) and pain intensity ≥4 on NRS.

5. Intervention

All participants receive 8 weekly intramuscular paravertebral O₂O₃ injections (10 µg/mL, 10 mL total).

After injections:

- Experimental group: McKenzie rehabilitation (10 sessions, 2 weeks)
- Control group: Back School program (10 sessions, 2 weeks)

6. Outcome Measures

- Primary: Neck Disability Index (NDI)
- Secondary: NRS, EQ-5D-3L, EQ-VAS

Assessments at baseline, post-injection, post-rehabilitation, and 24-week follow-up.

7. Statistical Analysis

Data will be analyzed using repeated measures ANOVA and t-tests. A p-value <0.05 will be considered statistically significant.