

Study Protocol

Official Title:

Effects of Cold Spray and Stress Ball Methods on Pain in Intramuscular Injection: A Randomized Controlled Trial

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1. Title of the Study

Effects of Cold Spray and Stress Ball Methods on Pain in Intramuscular Injection: A Randomized Controlled Trial

2. Objectives

To compare the effectiveness of cold spray and stress ball squeezing methods on reducing pain during intramuscular (IM) injections in adult patients, relative to standard care.

3. Study Design

This is a single-blind, three-arm, parallel-group, randomized controlled trial. The study follows CONSORT 2010 guidelines for reporting randomized trials.

4. Participants

- Adults aged 18–65 years
- Presenting to the emergency department with a prescription for IM diclofenac sodium
- Able to understand and speak Turkish
- No sensory impairments (vision/hearing)
- No skin lesions, scars, or infections at the injection site
- No known allergy to diclofenac sodium

Exclusion Criteria:

- Neurological conditions affecting pain perception (e.g., hemiplegia, paresthesia)
- Recent IM injection in both ventrogluteal areas (last 2 weeks)
- Abnormal BMI (<18.5 or >24.9 kg/m²)
- Cold intolerance

5. Sample Size and Randomization

The sample size was determined using G*Power 3.1.9.7, with an effect size ($d = 0.63$), 95% confidence, and 80% power, resulting in 66 participants (22 per group).

Randomization was performed using www.random.org. Participants were assigned to one of the following groups:

- Group 1: Cold Spray
- Group 2: Stress Ball
- Group 3: Control (Standard IM injection only)

Allocation concealment was ensured using opaque sealed envelopes.

6. Intervention Methods

- Cold Spray Group: A cold spray (Galena®, containing butane, propane, isobutane) was applied to a 10 cm² area at the injection site from a 15 cm distance for 5 seconds before injection.
- Stress Ball Group: Patients squeezed a medium-hard silicone stress ball rhythmically using the opposite hand during the injection.
- Control Group: Standard IM injection procedure without any additional intervention.

7. Injection Protocol

- IM Diclofenac sodium (3 mL)
- 21G needle, 5 mL syringe
- Injection into randomly assigned ventrogluteal region
- Skin disinfection with alcohol
- Air-lock technique (0.2–0.3 mL)
- 90° angle insertion
- Aspiration (5 seconds)
- Injection duration: 30 seconds (1 mL per 10 sec)
- Needle removal after 10 seconds
- Gentle pressure for 15–20 seconds

8. Outcome Measures

- Primary outcome: Pain intensity measured within 1 minute post-injection using the Visual Analog Scale (VAS: 0 = no pain, 10 = worst possible pain)

9. Data Collection Tools

- Patient Information Form: Includes demographic and clinical variables (age, sex, BMI, education level, chronic disease status)
- VAS Scale: Used by an independent nurse blinded to group allocation

10. Statistical Analysis Plan

- Descriptive statistics: mean, standard deviation, min–max
- Chi-square or Fisher's Exact Test: for categorical variable comparison
- Student's t-test: comparison of mean VAS scores between groups
- Significance level: $p < 0.05$

11. Ethical Considerations

- Ethics approval obtained from Gümüşhane University Ethics Committee (Approval No: E-95674917-108.99-291198)
- Written informed consent obtained from all participants
- Participant anonymity and data confidentiality maintained

12. Funding and Conflict of Interest

- No external funding received
- No conflict of interest declared by authors

13. Investigators and Roles

- Handan Aydın Kahraman: Study design, Data analysis, manuscript writing
- Esra Aydın: Study design, supervision, manuscript writing
- İbrahim Nas: Data collection, supervision, manuscript writing