

**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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Study Protocol: Effects of Cold Spray and Stress Ball Methods on Pain in Intramuscular Injection

## 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/m<sup>2</sup>)
- 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](http://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 cm<sup>2</sup> 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