

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparing effects of two muscular injection methods on site-pain intensity of injection

#### Protocol summary

##### Summary

Injections are among the most frequently used medical procedures, with more than 12 billions injections administered each year world-wide. In spite of the wide use of the procedure, pain associated with injection remains an unsolved problem of the contemporary medical practice. Reducing patients' pain is important for all nurses for many reasons. Unnecessary pain can damage the nurse—patient relationship and may also lead to dangerous syncopal attacks. The aim of this study is to compare of effects of two muscular injection methods on site-pain intensity of injection in patients who refer to injections ward of Kamkar-Arabnia hospital, Qom, Iran, in 2010. In this work, 75 women with ages from 16-60 years who have penicillin injection intramuscularly in a health centre will be studied. The samples are chosen randomly divided into three groups: the first group will receive intramuscular injection with the application of the blunt pins, the second group will receive local cold therapy and the third group (the control group) will receive routine care. Pain will be tested with the visual analogue scale on a 0 (no pain)-10 (maximum pain) scale.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201011012560N4**

Registration date: **2010-12-02, 1389/09/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-12-02, 1389/09/11

##### Registrant information

##### Name

Mohammad reza Yeganehkhah

##### Name of organization / entity

Qom University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6630 4368

##### Email address

yeganehkhah@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qom University of Medical Sciences and Health Services

##### Expected recruitment start date

2010-11-22, 1389/09/01

##### Expected recruitment end date

2011-02-20, 1389/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing effects of two muscular injection methods on site-pain intensity of injection

##### Public title

Comparing effects of two muscular injection methods on site-pain intensity of injection

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: 1) Women aged 18-80 years. 2) Having order to receive Penicillin 6.3.3 as a IM injection. 3) Having no sensitivity to Penicillin. 4) Oriented to person/ place/ time/ situation. 5) Ability of patient to assess the

pain with visual analogue scale. 6) Ability of patient to looking and listening. Exclusive criteria: 1) Having pain in the injection site. 2) BMI less than 18.5 and more than 30. 3) Having wound or scar in the injection site. 4) Absence of collaboration.

## Age

From **16 years** old to **60 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **75**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

The sample size of the study was calculated with power of 80% and significance level of 5% according with the result of previous studies.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Qom University of Medical Sciences and Health Services

##### Street address

Qom University of Medical Sciences and Health Services, Saheli st., Qom., Iran.

##### City

Qom

##### Postal code

37185

#### Approval date

2010-10-21, 1389/07/29

#### Ethics committee reference number

12050/34/س

## Health conditions studied

### 1

#### Description of health condition studied

pain

#### ICD-10 code

R52.0

#### ICD-10 code description

Acute pain

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

Before and after intramuscular injection

#### Method of measurement

Visual Analogue pain Scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

(1) In the first group, injections will perform with a plastic device, that consists of an oval disk (54 mm×40 mm) that supports multiple blunt pins (9 pins per cm<sup>2</sup>). In the middle of the oval support there is a hole of 5 mm of diameter. The use of the device is the following: first it is put on the skin at the injection site, then the injection needle is inserted in the hole of the device until it reaches the skin, without penetrating it; the device is then gently, but firmly, pressed onto the skin immediately prior and during the penetration of the injection needle into the skin. The device does not interfere with the needle penetration or with the drug delivery and there is no contact between the device and the injection needle.

#### Category

Other

### 2

#### Description

(3) In the control group, a standard injection is give with no further intervention as it is routine in most hospitals.

#### Category

N/A

### 3

#### Description

(2) In the second group(cold therapy), the subjects will inform that a 2—3 cm piece of ice would be placed on the injection site on the gluteal muscle for 30 s prior to injection.

#### Category

Other

## Recruitment centers

1

#### Recruitment center

**Name of recruitment center**

Kamkar-Arabnia hospital

**Full name of responsible person**

**Street address**

**City**

Qom

Saeedi highway

**City**

Tehran

**Postal code**

**Phone**

+98 21 6630 4368

**Fax**

**Email**

yeganeh3603@yahoo.com

**Web page address**

## Sponsors / Funding sources

1

#### Sponsor

**Name of organization / entity**

Qom University of Medical Sciences and Health Services

**Full name of responsible person**

Ali Salimi

**Street address**

Saheli st.

**City**

Qom

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Qom University of Medical Sciences and Health Services

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Qom University of Medical Sciences and Health Services

**Full name of responsible person**

Mohammad Reza Yeganeh khah

**Position**

MSc in Community Health Nursing

**Other areas of specialty/work**

**Street address**

No. 12, 2 Senobar lane., Sepideh Ave., Bahrami st.,

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Qom University of Medical Sciences and Health Services

**Full name of responsible person**

Mohammad Reza Yeganeh khah

**Position**

MSc in Community Health Nursing

**Other areas of specialty/work**

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yeganeh3603@yahoo.com

**Web page address**

## Person responsible for updating data

#### Contact

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty