

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Effect of cold compress on the pain of intramuscular injection of penicillin G benzathine in adult males

#### Protocol summary

##### Summary

The aim of this randomized clinical trial is to determine the effect of cold compress on pain of intramuscular injection of penicillin G benzathine in adult males. Inclusion criteria: age 15-50 years old; penicillin G benzathine prescription by a physician; educational level of at least secondary school; no problem at injection site; willingness to participate in the study. Exclusion criteria: presence of any kind of pain before the injection; unwillingness to participate in the study; clogging of needles during injection; sensory and motor disorders; diabetes mellitus; severe pain for another reason; presence of communication problems. In this study 100 patients in the clinic of Imam Khomeini hospital of Esferayen whom were prescribed penicillin G benzathine were randomly allocated into intervention and control groups. Randomization will be done using sealed envelopes. The intervention group received a cold compress with a 2-8 °C on the dorsogluteal muscle for 5 minutes before intramuscular injection. Injection for the control group will be done in a routine method. The researcher will administer the drug for both groups. The severity of pain will be measured using the Visual Analog Scale during, immediately and 5 minutes after injection (Scale VAS).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016091229797N1**  
Registration date: **2016-12-22, 1395/10/02**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-22, 1395/10/02

#### Registrant information

##### Name

Hamid Zohrabi

##### Name of organization / entity

Esfarāyen University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3723 8976

##### Email address

zohrabi.h@esfrums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for research of Esfarayen University of Medical Sciences

#### Expected recruitment start date

2016-09-22, 1395/07/01

#### Expected recruitment end date

2017-04-04, 1396/01/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of cold compress on the pain of intramuscular injection of penicillin G benzathine in adult males

#### Public title

Effect of cold compress on intramuscular injection pain

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: age 15-50 years old; penicillin G benzathine prescription by a physician; educational level of at least secondary school; no problem at injection site; willingness to participate in the study. Exclusion criteria:

presence of any kind of pain before the injection; unwillingness to participate in the study; clogging of needles during injection; sensory and motor disorders; diabetes mellitus; severe pain for another reason; presence of communication problems.

**Age**

From **15 years** old to **50 years** old

**Gender**

Male

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomization will be done using sealed envelopes.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Esfarayen University of Medical Sciences

**Street address**

Imam Reza street.

**City**

Esfarāyen.

**Postal code**

9661856188

**Approval date**

2016-01-06, 1394/10/16

**Ethics committee reference number**

IR- ESFARAYENUMS.REC.1394.12

**Health conditions studied****1****Description of health condition studied**

Intramuscular injection

**ICD-10 code**

-

**ICD-10 code description**

-

**Primary outcomes****1****Description**

Pain severity

**Timepoint**

Three times: during injection, immediately after the injection and 5 minutes after injection.

**Method of measurement**

VAS Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control Group: In this group, the injection will be done according to routine method and pain severity will be measured during, immediately and 5 minutes after injection.

**Category**

Treatment - Other

**2****Description**

Intervention group: In this group participants will receive a 5 minute cold compress with an ice pack on dorsogluteal muscle before the injection. The severity of pain will be measured during, immediately, and 5 minutes after the injection.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Esfarāyen's Imam Khomeini (RA) Hospital

**Full name of responsible person**

Hamid Zohrabi

**Street address**

Imam Reza Ave

**City**

Esfarāyen

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Esfarayen University of Medical Sciences

**Full name of responsible person**

Eshagh Ildarabadi  
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Esfarayen  
**Grant name**  
-  
**Grant code / Reference number**  
-  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Vice Chancellor for research of Esfarayen University of Medical Sciences  
**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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*