

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

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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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Imam Reza street
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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

Contact

Name of organization / entity
Esfarāyen University of Medical Sciences
Full name of responsible person
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Web page address

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