Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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+98 58 3723 8976
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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

Street address

Imam Reza street

City

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

Mahmod Marhamati

Position

MSc Medical-surgical nursing

Other areas of specialty/work

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Position

Nursing Student

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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