

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Effect of Lidocaine 2% gel on severity of pain during testing and intramuscular penicillin Benzathin (1/200/000 U) injection

Protocol summary

Summary

The aim of this study was to determine the effect of lidocaine 2% gel on intensity of pain during testing and intramuscular Benzathin (1/200/000 u) injection. In this clinical trial, 60 patients for whom injection of Benzathin Penicillin had been prescribed were chosen and randomly assigned into intervention or control. The patients in the intervention group lidocaine 2% gel was applied 10 minutes before testing at the site of intramuscular injection while in the control group, routine testing and IM injection was performed. Intensity of pain was measured using Visual Analogue Scale (VAS) and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904024247N1**

Registration date: **2009-05-22, 1388/03/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-05-22, 1388/03/01

Registrant information

Name

Abolfazl Farhadi

Name of organization / entity

Islamic Azad University, Shirvan Branch,

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shirvan branch, Azad Islamic University

Expected recruitment start date

2009-05-22, 1388/03/01

Expected recruitment end date

2009-09-24, 1388/07/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Lidocaine 2% gel on severity of pain during testing and intramuscular penicillin Benzathin (1/200/000 U) injection

Public title

Effect of Lidocaine 2% gel on severity of pain during testing and intramuscular penicillin Benzathin (1/200/000 U) injection

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: age 15-50 years, prescription of injection of penicillin by a physician, no other injections prescribed, full consciousness, Exclusion criteria: any other pain before injection, blocked needle leading to a delay during injection, communication difficulties, presence of severe pain due to other cause, presence of diabetes mellitus, presence of any sensory-motor disorders, any other problem at the site of injection, receiving penicillin injection during 6 months prior to the study

Age

From **16 years** old to **50 years** old

Gender

Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ninth region, Islamic Azad University

Street address
No. 225, Chamran St.

City
Mashhad

Postal code
94617

Approval date
empty

Ethics committee reference number
09/88/5/1385

Health conditions studied

1

Description of health condition studied
pain during testing and intramuscular penicillin Benzathin

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of pain

Timepoint
5 minute after penicillin testing or IM injection

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Applying 3 grams lidocaine 2% gel in 9 cm area, 10 minutes before testing or IM injection and then testing or intramuscular injection of Penicillin Benzathin 1200000 u

Category
Treatment - Drugs

2

Description
Testing or intramuscular injection of Penicillin Benzathin 1200000 u

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Dr. Rohani

Street address
Imam Reza St

City
Shirvan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University, Shirvan Branch

Full name of responsible person
Dr Mehdi Vatanparast

Street address
Islamic Azad University, Shirvan Branch, University St

City
Shirvan

Grant name
پژوهشی

Grant code / Reference number

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

Title of funding source
Islamic Azad University, Shirvan Branch

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***Postal code**

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity****Full name of responsible person**

Abolfazl Farhadi

Position

Master of Nursing/ Reasercher Assistant

Other areas of specialty/work**Street address**

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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*