Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 minate after penicillin testing or IM injection
Method of measurement
Visual Analouge 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

Person responsible for general inquiries

Contact
Name of organization / entity
Full name of responsible person
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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