

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of anesthetic effects of lidocaine injected with jet injecor with lidocaine injected with neeedle and siryngie in lumbar puncture in patients admitted to Shariati and Imam Khomeini Hospital

Protocol summary

Summary

Objective: To evaluate effectiveness of needle free injection of lidocaine via Jet injectore device to induce analgesia in lumbar puncture. Inclusion criteria: All of patients who are candidate for lumbar puncture and are above 18 years old and also sign consent form enrolled in the study. Exclusion criteria: unwilling of patients to participate in the study and also relative or absolute contraindication of lumbar puncture such as; in site infection, coagulative disorders, ICP rising and etc. are main exclusion criteria of the study. Study population: All patients who come to emergency department of Shariati and Imam Khomeni Hospitals and are candidate for lumbar puncture. Sample size: Considering of confidence interval 99%, power 90% we need to 22 patients in each group of the study. Standard deviation for patients= 5.5 $\pm$ 3.2 and controls= 2.5 $\pm$ 1.9. Interventions: This is a single blinded clinical trial and patients randomly assigned to case or control groups. In cases, patients receive 0.5 cc lidocainte 2% via Jet injector and in controls they receive 3- 4 cc lidocane 2% via syringe to introduce local analgesia. Physician performs lumbar puncture after inducing of analgesia lumbar. In both groups pain level of patients after inducing analgesia and performing lumbar puncture evaluate with Numerical Rating Scale by investigators.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407048872N4**

Registration date: **2014-07-24, 1393/05/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-24, 1393/05/02

Registrant information

Name

Morteza Saeedi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-07-21, 1393/04/30

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anesthetic effects of lidocaine injected with jet injecor with lidocaine injected with neeedle and siryngie in lumbar puncture in patients admitted to Shariati and Imam Khomeini Hospital

Public title

local anesthetic effect of lidocaine in lumbar puncture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age > 18; clinical indication of lumbar puncture. Exclusion criteria: in site infection; coagulative disorders; ICP rising; decrease level of consciousness; mass lesion in brain CT scan; lidocaine sensitivity; moderate to severe pain; uncooperative patients; unwilling to participation; severe renal and hepatic disfunction.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Qods street, keshavarz Blvd

City

Tehran

Postal code

Approval date

2014-04-08, 1393/01/19

Ethics committee reference number

37/130/93/۵

Health conditions studied

1

Description of health condition studied

local anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

pain evaluation

Timepoint

After local anesthesia, After performing lumbar puncture

Method of measurement

Neumeric Rating Scale

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

After termination of Procedure

Method of measurement

beck questionnaire

2

Description

Physician satisfaction

Timepoint

After termination of procedure

Method of measurement

Beck questionarry

Intervention groups

1

Description

In intervention group, each patient receives 0.5 cc lidocaine 2% via Jet injector. The device hold 0.5 cm above the skin of injection site and then lidocaine inject to induce of analgesia.

Category

Treatment - Devices

2

Description

In controls 3- 4 cc lidocaine 2% inject via syringe in lumbar puncture site. The rest of procedure will done in both group as routine and completely similar.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Morteza Saeedi

Street address

North Amirabad street
City
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2

Recruitment center

Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Majid Hajimaghsoudi
Street address
East Bagherkhan street, Chamran highway
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
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Shahin Akhondzadeh Basti
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Building No 1, North entrance door of Tehran
University, Poursina street, Qods street, Enghelab
street
City
Tehran
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Tehran 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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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