

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of midazolam on prevention of post dural puncture headache

Protocol summary

Study aim

The aim of this study was to evaluate the effect of midazolam on decreasing incidence of post-dural puncture headache and decreasing the severity of post-dural puncture headache and reducing its duration.

Design

This study was a single blind randomized controlled clinical trial on 120 patients aged 18-60 years who were candidates for diagnostic dural puncture.

Settings and conduct

This study was done on a single blind randomized controlled clinical trial on 120 patients aged 18-60 years who were candidates for diagnostic lumbar puncture referred to Ahvaz Golestan Hospital. Patients were divided into two equal groups of intervention and control (number = 60) by block randomization and they had no awareness of grouping way. 5 minutes before lumbar puncture the intervention group had received 3 milligram Intravenous midazolam and the control group also received normal saline as placebo. Both groups were anesthetized with lidocaine and lumbar puncture was performed with Quincke needle 20 gauge in sterile and supine position. They were evaluated for incidence, onset, severity, and duration of headache. The severity of headache was measured using the visual analog scale.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18-60 years old Undergoing diagnostic LP for any indication Exclusion Criteria: Any known chronic pulmonary disease Known sensitivity to Benzodiazepines Decreased level of consciousness or other conditions that the patient is unable to tell us about his headache. pregnancy

Intervention groups

Intervention group: receiving intravenous midazolam
Control group: receiving normal saline

Main outcome variables

1. Rate of post dural puncture headache 2. Severity of post dural puncture headache 3. Duration of post dural puncture headache 4. Onset of post dural puncture headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038631N1**

Registration date: **2019-09-29, 1398/07/07**

Registration timing: **retrospective**

Last update: **2019-09-29, 1398/07/07**

Update count: **0**

Registration date

2019-09-29, 1398/07/07

Registrant information

Name

Mansoure Babadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3012

Email address

babadi.mansoureh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-20, 1397/02/30

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-05-20, 1397/02/30

Actual recruitment end date

2019-02-19, 1397/11/30

Trial completion date

2019-02-23, 1397/12/04

Scientific title

The effect of midazolam on prevention of post dural

puncture headache

Public title

The effect of midazolam on headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Undergoing diagnostic lumbar puncture for any indication 18 to 60 years old

Exclusion criteria:

Any known chronic pulmonary disease Known sensitivity to benzodiazepines Decreased level of consciousness or other conditions that the patient is unable to tell us about his headache. Pregnancy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization method was used for randomization. Thirty blocks were created by www.randomizer.org. The blocks were the same size and equal to 4. In each block, there were two allocations for the intervention group and two allocations for the control one. In each block, 1 and 2 numbers were given in different order, which determined the group of patients. Number one was considered as intervention group and number two was used as control group. Patients were randomly assigned to intervention or control groups after being nominated for lumbar puncture on the basis of one and two numbers in blocks. Also the random sequence of blocks was in the hands of an individual other than the researcher who, by telephone, provided only the required number indicating the intervention or control group. Without researchers intervention, the patients were assigned to each groups based on numbers. After sampling accomplished, each groups had the same size with number of 60.

Blinding (investigator's opinion)

Single blinded

Blinding description

None of the patients in this study knew that they were in the intervention or control group and that the treatment received was either drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Development Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Esfand Avenue, Golestan Blvd, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-05-19, 1397/02/29

Ethics committee reference number

IR.AJUMS.REC.1397.138

Health conditions studied

1

Description of health condition studied

Post dural puncture headache

ICD-10 code

G97.1

ICD-10 code description

Other reaction to spinal and lumbar puncture

Primary outcomes

1

Description

Incidence of post dural puncture headache

Timepoint

This evaluation was performed at 6, 12, 24, 48, 72 and on the fourth and fifth days after lumbar puncture.

Method of measurement

Diagnostic criteria of the International Classification of Headache Disorders, third edition (beta version)

2

Description

The severity of post dural puncture headache

Timepoint

This evaluation was performed at 6, 12, 24, 48, 72 and on the fourth and fifth days after lumbar puncture.

Method of measurement

Visual Analogue Scale

3

Description

The duration of post dural puncture headache

Timepoint

This evaluation was performed at 6, 12, 24, 48, 72 and on the fourth and fifth days after lumbar puncture.

Method of measurement

Daily headache diary

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 3 milligram midazolam diluted in normal saline and volume of 5 milliliter was injected intravenously five minutes before dural puncture in single dose.

Category

Treatment - Drugs

2

Description

Control group: Only 5 milliliter normal saline was injected intravenously five minutes before dural puncture in single dose.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Mansoureh Babadi

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Sponsors / Funding sources

1

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Full name of responsible person

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itc@ajums.ac.ir

Web page address

http://vchresearch.ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Davood Kashipazha

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available