

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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](http://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

##### **Street address**

Department of Neurology, Golestan Hospital,  
Farvardin St., Golestan, Ahvaz

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### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

Mohammad Badavi

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Development Research and Technology, Ahvaz  
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##### **Email**

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**

Neurology

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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