Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 awarness 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

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Iran (Islamic Republic of)

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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 accomplisehed, 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, Ahwaz 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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Department of Neurology, Golestan Hospital, Farvardin St., Golestan, Ahvaz
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Sponsors / Funding sources

1

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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
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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