

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of intranasal midazolam with topical lidocaine ointment with intranasal midazolam alone on the success of blood draw and cerebrospinal fluid retrieval

Protocol summary

Study aim

Comparison of the effect of intranasal midazolam with topical lidocaine ointment with intranasal midazolam alone on the success of blood draw and cerebrospinal fluid retrieval

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 80 patients. In order to randomize, the block randomization method will be used.

Settings and conduct

In this study, all children who go to Ali Asghar Hospital for blood sampling and cerebrospinal fluid collection will be included in the study. Children will be randomly divided into 2 groups based on size 8 blocks. The sample size for each study group will be 40 people. A total of 80 patients will be screened. They will be child caregivers and information analysts will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children older than 1 years old; suffering from a variety of neurological and infectious diseases. Exclusion criteria: children over 7 years old; weight less than 10 kg; decreased level of consciousness; underlying neurological impairment; use of analgesics 12 hours before puncture; acute or chronic respiratory, renal, and hepatic disorders.

Intervention groups

Intervention group: Children will receive intranasal midazolam with lidocaine ointment topically in the process of blood sampling and cerebrospinal fluid collection, and each person will be given 5 to 10 micrograms per kilogram of nasal midazolam weight with lidocaine ointment. Control group: Children receive intranasal midazolam alone during blood sampling and cerebrospinal fluid collection, and each person will be given 5 to 10 micrograms per kilogram of intranasal midazolam weight.

Main outcome variables

Respiratory disorders; The amount of pain; Percentage of oxygen saturation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151003024317N13**

Registration date: **2022-01-19, 1400/10/29**

Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**

Update count: **0**

Registration date

2022-01-19, 1400/10/29

Registrant information

Name

Mahdi Rezai

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of intranasal midazolam with topical lidocaine ointment with intranasal midazolam alone on the success of blood draw and cerebrospinal fluid retrieval

Public title
Effect of intranasal midazolam with topical lidocaine ointment on the success of blood draw and cerebrospinal fluid retrieval

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children over 1 year Suffering from a variety of neurological and infectious diseases
Exclusion criteria:
Children over 7 years Weight less than 10 kg Decreased level of consciousness Underlying neurological impairment Use of analgesics 12 hours before puncture Acute or chronic respiratory, renal, and hepatic disorders

Age
From **1 year** old to **7 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to two groups by using a random number table. In order to randomize, a random block method will be used. For this purpose, we formed blocks of size 8. In each block, 4 individuals will be in intervention group and 4 will be in control group. A total of 10 blocks will be considered for the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients (child caregivers) will be unaware and blind to the type of treatment. To hide, similar ointments were used, without the drug name tag and only with the code. Child caregivers will be aware that they will be randomly assigned to one of the two treatment groups, but will not know which treatment will be offered in that group. Children will be placed in one of two groups using a table of random numbers. The clinician also knows that children will be treated in two different ways, but will not know which method will be used for each child. The data collector, analyst and outcome assessor will collect and

analyze the information based on groups 1 and 2 and will not be aware of the type of treatment provided in the groups and will be kept blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535

Approval date
2021-06-29, 1400/04/08

Ethics committee reference number
IR.IUMS.REC.1400.310

Health conditions studied

1

Description of health condition studied
Cerebrospinal fluid retrieval

ICD-10 code
G97.0

ICD-10 code description
Cerebrospinal fluid leak from spinal puncture

Primary outcomes

1

Description
Respiratory disorders

Timepoint
After blood sampling and cerebrospinal fluid collection, 3 hours, 6 hours and 12 hours after that

Method of measurement
Based on the information recorded in patient's record

2

Description
The amount of pain

Timepoint

After blood sampling and cerebrospinal fluid collection, 3 hours, 6 hours and 12 hours after that

Method of measurement

Based on the information recorded in patient's record

3

Description

Percentage of oxygen saturation

Timepoint

After blood sampling and cerebrospinal fluid collection, 3 hours, 6 hours and 12 hours after that

Method of measurement

Based on the information recorded in patient's record

Secondary outcomes

1

Description

Heart rate

Timepoint

After blood sampling and cerebrospinal fluid collection, 3 hours, 6 hours and 12 hours after that

Method of measurement

Based on the information recorded in patient's record

2

Description

Respiratory rate

Timepoint

After blood sampling and cerebrospinal fluid collection, 3 hours, 6 hours and 12 hours after that

Method of measurement

Based on the information recorded in patient's record

Intervention groups

1

Description

Intervention group: children will receive intranasal midazolam with lidocaine ointment topically in the process of blood sampling and cerebrospinal fluid collection, and each person will be given 5 to 10 micrograms per kilogram of nasal midazolam weight with lidocaine ointment.

Category

Treatment - Drugs

2

Description

Control group: Control group: Children receive intranasal midazolam alone during blood sampling and cerebrospinal fluid collection, and each person will be given 5 to 10 micrograms per kilogram of intranasal midazolam weight.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Educational and Medical Center

Full name of responsible person

Shaqayeq Khosravi

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No. 198, Vahid Dastgerdi St, after Mirdamad Bridge, Modares Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

shaqayeq.khosravi@gmail.com

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shaqayeq Khosravi

Position

Assistant 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