Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of midazolam alone and midazolam with maternal presence in lumbar puncture of 6-24 month old children

Protocol summary

Summary

This study will be done to answer this question that whether or not intravenous midazolam with maternal presence is more efficient than intravenous midazolam alone in reduction of pain and anxiety of lumbar puncture (LP) in 6-24 month old children. In a single blind clinical trial, sixty 6-24 month old children, who are to be admitted to Pediatric Ward of Shahid Sadoughi Hospital, Yazd, Iran and doing of LP is necessary based on clinical judgment of pediatricians, will be distributed randomly into two groups. In both groups, 0.5 mg/kg midazolam intravenously will be injected five minutes before LP. In group I, lumbar puncture will be done with maternal presence and in group II, mother is out of the room. Primary outcomes include anxiety score before skin needle insertion and pain score during needle insertion to skin for LP. Secondary outcomes include success rate in reducing of anxiety during skin needle insertion (anxiety score of four and more three) and success rate in reducing of pain when the needle will be inserted to skin for LP (pain score of less than three). The trial uses computer generated equal simple randomization by random numbers and data collectors, outcome assessors and data analysts are kept blinded to the allocation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609222639N19**
Registration date: **2016-10-01, 1395/07/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-01, 1395/07/10

Registrant information

Name
Razieh Fallah

Name of organization / entity
Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country
Iran (Islamic Republic of)

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+98 35 3822 4000

Email address
fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-07-22, 1394/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of midazolam alone and midazolam with maternal presence in lumbar puncture of 6-24 month old children

Public title

Clinical trial of efficacy evaluation of midazolam alone and midazolam with maternal presence on reduction of pain and anxiety of lumbar puncture of 6-24 month old children

Purpose

Other

Inclusion/Exclusion criteria
Inclusion criteria: Age range of 6-24 months; undergone lumbar puncture based on clinical judgment of the pediatrician; not received sedative hypnotic drugs within the past 48 hours Exclusion criteria: Neurodevelopmental delay or mental retardation; loss of consciousness (Glasgow coma scale less than 12); symptoms of increased intracranial pressure; done lumbar puncture more than two times; previously undergone lumbar puncture
Age
From **6 months** old to **2 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Yazd Medical Sciences University,Yazd, Iran
Street address
Central building of university, Bahonar square
City
Yazd
Postal code
Approval date
2015-03-17, 1393/12/26
Ethics committee reference number
IR.SSU.MEDICINE.REC.13930128

Health conditions studied

1

Description of health condition studied
Other disorders of central nervous system
ICD-10 code
G90-G99
ICD-10 code description
Other disorders of central nervous system

Primary outcomes

1

Description
Anxiety score before skin needle insertion for lumbar puncture
Timepoint
Before skin needle insertion for lumbar puncture
Method of measurement
Questionnaire

2

Description
Pain score during needle insertion to skin
Timepoint
During needle insertion to skin for lumbar puncture
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Success rate in reducing of anxiety during skin needle insertion (anxiety score of four and more three)
Timepoint
During needle insertion to skin for lumbar puncture
Method of measurement
Questionnaire

2

Description
Success rate in reducing of pain (pain score of less than three)
Timepoint
During needle insertion to skin for lumbar puncture
Method of measurement
Questionnaire

Intervention groups

1

Description
0.5 mg/kg midazolam ampule of 5 mg/milliliter from Aburaihan Co. Tehran, Iran will be injected five minutes before lumbar puncture and mother will be out of the room during lumbar puncture of her child
Category
Other

2

Description

0.5 mg/kg midazolam ampule of 5 mg/milliliter from Aburaihan Co. Tehran, Iran will be injected five minutes before lumbar puncture and during lumbar puncture of the child, mother will be in the room and sit face to face of her child and catch child hand in her hand and dandle it while the mother and she is face to face of the person performing the lumbar puncture

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital - Pediatric ward

Full name of responsible person

Dr.Rihanah Esteghamat

Street address

hahid Sadoughi Hospital, Ebnsina Blvd, Shahid Ghandi Blvd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Dr.Amirhoshang Mehrparvar

Street address

Central building of university, Bahonar Square

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

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

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Dr. Farzad Ferdosian

Position

Subspecialty in Pediatric Infectious Disease, Assistant Professor

Other areas of specialty/work

Street address

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Person responsible for updating data

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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