

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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)

Phone

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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

Shahid 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

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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