

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of sitting and lateral decubitus position in lumbar puncture of children

#### Protocol summary

##### Study aim

Comparison of success rate of lumbar puncture in lateral decubitus versus sitting position

##### Design

Randomized, not-blinded, parallel-group clinical trial

##### Settings and conduct

In this open labeled, parallel-group clinical trial, we compared success rate of lumbar puncture in lateral decubitus and sitting position.

##### Participants/Inclusion and exclusion criteria

1 to 5-year-old children who need lumbar puncture

##### Intervention groups

In group I, lumbar puncture was performed in lateral decubitus position, and in group II, lumbar puncture was performed in sitting position.

##### Main outcome variables

Rate of successful lumbar puncture; baseline anxiety and pain scores during lumbar puncture

#### General information

##### Reason for update

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20091027002639N22**

Registration date: **2020-03-16, 1398/12/26**

Registration timing: **retrospective**

Last update: **2020-03-16, 1398/12/26**

Update count: **0**

##### Registration date

2020-03-16, 1398/12/26

##### Registrant information

##### Name

Razieh Fallah

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,  
Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3822 4000

##### Email address

fallah@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-22, 1398/03/01

##### Expected recruitment end date

2019-09-22, 1398/06/31

##### Actual recruitment start date

2019-05-22, 1398/03/01

##### Actual recruitment end date

2019-09-22, 1398/06/31

##### Trial completion date

2019-09-22, 1398/06/31

##### Scientific title

Effect of sitting and lateral decubitus position in lumbar puncture of children

##### Public title

Comparison of success rates of performing lumbar puncture in 1-5 year-old children in lateral decubitus versus sitting position

##### Purpose

Other

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Children aged 1-5 years With the American Society of Anesthesiologists (ASA) physical status I-II 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;

#### Age

From **1 year** old to **5 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

Actual sample size reached: **80**

More than 1 sample in each individual

Actual sample size in each individual: **1**

1

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple randomization by random numbers

#### 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

##### Province

Yazd

##### Postal code

8915887857

#### Approval date

2019-05-19, 1398/02/29

#### Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.067

## 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

Rate of successful lumbar puncture

#### Timepoint

During needle insertion to skin for lumbar puncture

#### Method of measurement

When the free flow of cerebrospinal fluid was observed upon the first attempt

### 2

#### Description

Anxiety score during needle insertion to skin

#### Timepoint

Before skin needle insertion for lumbar puncture

#### Method of measurement

Questionnaire

### 3

#### 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

Intervention group 1: 0.5 mg/kg midazolam ampule of 5 mg/milliliter from Aburaihan Co. Tehran, Iran will be injected five minutes before lumbar puncture and lumbar puncture of child will be done in sitting position

**Category**

Other

**2****Description**

Intervention group 2: 0.5 mg/kg midazolam ampule of 5 mg/milliliter from Aburaihan Co. Tehran, Iran will be injected five minutes before lumbar puncture and lumbar puncture of child will be done in lateral decubitus position

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Sadoughi Hospital - Pediatric ward

**Full name of responsible person**

Dr.Zeynab Dehghani

**Street address**

Shahid Sadoughi Hospital, Ebnsina Blvd, Shahid Ghandi Blvd

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zeynab.1395@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr.Masoud Mirzaei

**Street address**

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mmirzaei@ssu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Farzad Ferdosian

**Position**

Subspecialty in pediatric infectious disease, Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Infectious diseases

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Dr. Razieh Fallah

**Position**

Professor, Pediatric Neurologist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Neurology

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**Person responsible for updating data**

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**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Farzad Ferdosian

**Position**

1. Subspecialty in pediatric infectious disease,  
Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Infectious diseases

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable