Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Ẅith 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

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4000

Fax

+98 35 3822 4100

Email

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

Central building of university, Bahonar Square

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3724 0171

Email

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

Street address

Shahid Sadoughi Hospital, Ebnsina Blvd, Shahid Ghandi Blvd

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4000

Fax

+98 35 3822 4100

Email

ferdosianfarzad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Razieh Fallah

Position

Professor, Pediatric Neurologist

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

Street address

Shahid Sadoughi Hospital, Ebnsina Blvd, Shahid Ghandi Blvd

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4000

Fax

+98 35 3822 4100

Email

dr.raziehfallah@yahoo.com

Person responsible for updating data

Contact

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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Phone

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Fax

+98 35 3822 4100

Email

ferdosianfarzad@yahoo.com

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