

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Evaluation of ultrasound-guided LP success rate in children under 24 months ; Randomized clinical trial with control group

#### Protocol summary

##### Study aim

Determining the success rate of performing LP with ultrasound in children under 24 months

##### Design

A concealed, randomized, sham controlled clinical trial with a parallel group design of 80 patients, enrolled in 2023

##### Settings and conduct

This clinical trial study will be performed on neonates under 24 months that needs LP referred to Taleghani Hospital in Gorgan in 2023.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 24 months and younger who needed to undergo a diagnostic or treatment procedure for LP Exclusion criteria: Known spinal abnormalities such as spina bifida and Mentally retarded parents of the patient No identification documents Absolute and relative contraindications of LP include: Skin infection at the site of skin puncture to perform LP, evidence of increased intracranial pressure, any space-occupying lesion in the cranial cavity, trauma, lumbar mass, change in mental capacity, focal nerve deficit, papillary edema, immunocompromised patients, recent seizure or any bleeding disease or coagulation defect

##### Intervention groups

The intervention group includes patients who, undergone portable ultrasound, mark the puncture site for lumbar puncture, and then perform lumbar puncture.

##### Main outcome variables

Success in doing LP

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221208056751N1**

Registration date: **2022-12-17, 1401/09/26**

Registration timing: **prospective**

Last update: **2022-12-17, 1401/09/26**

Update count: **0**

##### Registration date

2022-12-17, 1401/09/26

##### Registrant information

###### Name

Parisa Moradi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 911 177 7042

###### Email address

atamann1393@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-10, 1401/10/20

##### Expected recruitment end date

2023-03-06, 1401/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of ultrasound-guided LP success rate in children under 24 months ; Randomized clinical trial with control group

##### Public title

Evaluation of ultrasound-guided LP success rate in children under 24 months

##### Purpose

Diagnostic

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Children aged 24 months and younger who needed to undergo a diagnostic or treatment procedure for LP

**Exclusion criteria:**

Known spinal abnormalities such as spina bifida and...  
Mentally retarded parents of the patient  
No identification documents  
Absolute and relative contraindications of LP include: Skin infection at the site of skin puncture to perform LP, evidence of increased intracranial pressure, any space-occupying lesion in the cranial cavity, trauma, lumbar mass, change in mental capacity, focal nerve deficit, papillary edema, immunocompromised patients, recent seizure or any bleeding disease or coagulation defect

**Age**

From **1 day** old to **24 months** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We use the block randomization method to randomize subjects into groups that result in equal sample sizes. At the beginning of the randomization process, we randomly choose one of the following blocks by randomly throwing the dice and divide the rest of the samples into 2 groups according to the order of the samples. A: intervention and B: control  
B A B A 2) B B A A 1) B A A B 4) A B B A 3) A A B B 6) A B A B 5)

**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 Golestan University of Medical Sciences

**Street address**

Golestan University of Medical Sciences,  
Gorgan, Shastkola road, Philosophical Higher Education Complex

**City**

Gorgan

**Province**

Golestan

**Postal code**

4934174515

**Approval date**

2022-09-07, 1401/06/16

**Ethics committee reference number**

IR.GOUMS.REC.1401.259

**Health conditions studied****1****Description of health condition studied**

Lumbar Puncture

**ICD-10 code**

G96

**ICD-10 code description**

Other disorders of central nervous system

**Primary outcomes****1****Description**

Lumbar Puncture success in first try

**Timepoint**

Immediately after the intervention

**Method of measurement**

Lumbar puncture success rate after the first attempt

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: With the help of portable ultrasound, the suitable place for lumbar puncture is marked and then lumbar puncture will be done from that place.

**Category**

Diagnosis

**2****Description**

Control group: With classical method, based on anatomical landmarks, lumbar puncture will be performed on control group patients.

**Category**

Diagnosis

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

Taleghani Hospital

**Full name of responsible person**

Dr. Leila Barati

**Street address**

Philosophical Higher Education Complex, Shast Kola  
Road, Gorgan

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+98 911 177 7042

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atamann1393@gmail.com

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

Gorgan University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Honarvar

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Philosophical Higher Education, Shast Kola Road,  
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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**

Gorgan 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**

Gorgan University of Medical Sciences

**Full name of responsible person**

Dr. Prisa Moradi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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

Gorgan University of Medical Sciences

**Full name of responsible person**

Dr. Parisa Moradi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available