

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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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**

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Full name of responsible person

Dr. Parisa Moradi

Position

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Latest degree

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Other areas of specialty/work

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

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Full name of responsible person

Dr. Parisa Moradi

Position

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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