

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Aug 2026

### Comparison of efficacy of melatonin and gabapentin in reducing of pain and anxiety of lumbar puncture in children

#### Protocol summary

##### Summary

Lumbar puncture is one of the most important diagnostic and therapeutic procedures in children which needs immobilization of the child. The purpose of this study is to compare efficacy and safety of melatonin and gabapentin in reduction of pain and anxiety of lumbar puncture in children. In the study , 90 children whom are admitted to Pediatric Ward of Shahid Sadoughi hospital and lumbar puncture is done in them for the first time , are evaluated . The children are distributed into three groups. In one group , 15 mg/kg of gabapentin is diluted with normal saline , in other one 0.3mg/kg of melatonin is diluted with normal saline and in third group , 5 milliliter normal saline as placebo will be given . In all groups, oral drug or placebo will be prescribed one hour before lumbar puncture . Anxiety score in every 15 minutes and during lumbar puncture , pain score when needle inserts to skin for lumbar puncture and side effects of drugs are to be compared .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112032639N7**

Registration date: **2011-12-11, 1390/09/20**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-12-11, 1390/09/20

##### 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

Research Deputy, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

##### Expected recruitment start date

2011-09-23, 1390/07/01

##### Expected recruitment end date

2012-03-19, 1390/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of efficacy of melatonin and gabapentin in reducing of pain and anxiety of lumbar puncture in children

##### Public title

Melatonin and gabapentin in pain of lumbar puncture in children

##### Purpose

Other

##### Inclusion/Exclusion criteria

Inclusion criteria: children aged one month -7 years; Without systemic diseases and ASA class I or II ; Lumbar puncture are done for the first time; No usage of sedative or hypnotic drugs in recent 48 hours Exclusion Criteria: History of drug allergy; Having neurodevelopmental delay or mental retardation; Loss of

consciousness and GCS less than 12

#### Age

To 7 years old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 90

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Shahid Sadoughi University of Medical Sciences, Yazd,  
Iran

###### Street address

Bahonar square

###### City

Yazd

###### Postal code

##### Approval date

2011-10-06, 1390/07/14

##### Ethics committee reference number

39321/1/17/پ

### 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

successful lumbar puncture without anxiety and pain

##### Timepoint

one hour after drug useage during lumbar puncture

##### Method of measurement

clinical exam

#### 2

##### Description

obtain of pain score less than 4 in reduction of pain

##### Timepoint

one hour after drug useage during lumbar puncture

##### Method of measurement

clinical exam

#### 3

##### Description

obtain of anxiety score 4 and more in reduction of  
anxiety of lumbar puncture in children.

##### Timepoint

one hour after drug useage during lumbar puncture

##### Method of measurement

clinical exam

### Secondary outcomes

#### 1

##### Description

side effects

##### Timepoint

one hour after drug usage

##### Method of measurement

clinical exam

#### 2

##### Description

mean of time to obtain antianxiety situation

##### Timepoint

every 15 minutes

##### Method of measurement

clinical exam

#### 3

##### Description

mean of time to obtain painless situation

##### Timepoint

one hour after drug usage during lumbar puncture

##### Method of measurement

clinical exam

### Intervention groups

#### 1

##### Description

single dose of oral 15 mg/kg of gabapentin is diluted with  
normal saline

##### Category

Treatment - Other

## 2

### Description

single dose of oral 0.3mg/kg of melatonin is diluted with normal saline

### Category

Treatment - Other

## 3

### Description

5 milliliter of oral normal saline

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sadoughi hospital - Pediatric ward

##### Full name of responsible person

Dr.Razieh Fallah

##### Street address

Shahid Sadoughi Hospital, Sina Blvd, Shahid Ghandi Blvd

##### City

Yazd

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Deputy of research -Shaheed Sadoughi University of Medical Sciences ,Yazd,Iran

##### Full name of responsible person

Dr. Fatemah Ezodinee

##### Street address

Bahonar Square ,University central building

##### City

Yazd

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Deputy of research -Shaheed 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

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,Iran

#### Full name of responsible person

Dr.razieh Fallah

#### Position

assisstant professor

#### Other areas of specialty/work

#### Street address

Shahid Sadoughi Hospital, Sina Blvd, Shahid Ghandi Blvd

#### City

Yazd

#### Postal code

#### Phone

+98 35 1822 4000

#### Fax

#### Email

FALLAH@ssu.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

## 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