

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 byilding

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