Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy of melatonin and oral midazolam in sedation for electroencephalography of children

Protocol summary

Summary

In a clinical trial, efficacy and safety of melatonin and oral midazolam in induction of sedation of 80 children 1-10years old referred to electroencephalography unit, will be evaluated. The patients will randomly be assigned to receive either 0.3 mg/kg/dose of melatonin or 0.75mg/kg oral midazolam until Ramsay score of four is attained and recording of EEG is done successfully. Vital signs, cyanosis, respiratory state, apnea and any side effect will be evaluated in children for two hours after drug use. Efficacy of drugs in sedation induction, time to induction of sedation, total stay time in EEG unit, serious adverse events (hypotension, hypoxia and cyanosis, severe vomiting, irritability, apnea, laryngospasm, and bradycardia), and caregiver's satisfaction are also compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107182639N5**
Registration date: **2011-07-24, 1390/05/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-24, 1390/05/02

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

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Email address

fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy for research of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

Expected recruitment start date

2011-07-23, 1390/05/01

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 oral midazolam in sedation for electroencephalography of children

Public title

Melatonin and oral midazolam in sedation for electroencephalography of children

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: age 1-18 years old; children who are referred to EEG center but don't obey, , class 1 or 2 of ASA Exclusion criteria: Presence of gastritis or any other serious systemic diseases, use of sedative in two days ago ; occurrence of severe systemic reaction wth drugs

Age

From **1 year** old to **10 years** 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
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not 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
Yazd, Bahonar square, central building university
City
Yazd
Postal code
Approval date
2011-07-13, 1390/04/22
Ethics committee reference number
44447/1/17/پ

Health conditions studied

1

Description of health condition studied
Epilepsy
ICD-10 code
G40- G47
ICD-10 code description
Episodic and paroxysmal disorders

Primary outcomes

1

Description
sedation induction with achieving of a level of four on the Ramsay scale
Timepoint
every 15 minutes
Method of measurement
clinical

2

Description
success in recording of EEG
Timepoint
one hour after drug use
Method of measurement
clinical

Secondary outcomes

1

Description
serious adverse events (hypotension, hypoxia and cyanosis, severe vomiting, irritability, apnea, laryngospasm, and bradycardia)
Timepoint
every 10 minutes
Method of measurement
clinical

2

Description
side effects
Timepoint
every 15 minutes
Method of measurement
clinical

3

Description
time to induction of sedation
Timepoint
every 15 minutes
Method of measurement
clinical

4

Description
caregiver’s satisfaction scale
Timepoint
after 2 hours of drug use
Method of measurement
asking from caregiver

5

Description
total stay time in EEG unit
Timepoint
every 30 minutes
Method of measurement
asking from parents

Intervention groups

1

Description

oral melatonin 0.3 mg/kg/dose

Category

Other

2

Description

oral midazolam 0.75mg/kg/dose

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital - EEG unit

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 -Shahid Sadoughi University of Medical Sciences , Yazd, Iran

Full name of responsible person

Dr. Fatemeh Ezoddini Ardakani

Street address

Bahonar square, central building of university

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 -Shahid 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

associate professor

Other areas of specialty/work

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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