

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

+98 35 3822 4000

##### 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 with 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**

**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