

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of efficacy of amitriptyline and melatonin in prophylaxis of headach in 5-15 year old migraineurs children

#### Protocol summary

##### Summary

Migraine is the most important and frequent type of headache in children. Prophylactic therapy should be considered if a child experiences more than two to four severe episodes monthly or is unable to attend school regularly. The purpose of this study is to compare efficacy and safety of amitriptyline and melatonin in prophylaxis of migraine headache in children. In this study , sixty 5-15 year old children with migraine headache whom were referred to pediatric neurology clinic of Shahid Sadoughi University of Medical Sciences and prophylactic therapy indicated in them , are evaluated . The children are distributed into two groups. In both groups, oral drug and in one dose at bed time will be prescribed. In one group , 1mg/kg/day of amitriptyline and in other one , 0.3mg/kg/day of melatonin will be given . Number , severity and disability score of migraine headache and side effects of drugs are to be compared before and three months after treatment .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201305292639N12**

Registration date: **2013-06-07, 1392/03/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-06-07, 1392/03/17

##### 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 of Research of Shahid Sadoughi Medical Sciences University

##### Expected recruitment start date

2013-06-09, 1392/03/19

##### Expected recruitment end date

2014-01-20, 1392/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of efficacy of amitriptyline and melatonin in prophylaxis of headach in 5-15 year old migraineurs children

##### Public title

Amitriptyline and melatonin in prophylaxis of of migraine in children

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. children aged 5-15 years 2. Having migraine headache based on International Headache Society Criteria 3. Having frequent ( one or more headache attack per week ) or disabling ( PedMIDAS more than 20) headaches that prophylactic therapy indicated in them . in one month 4. not used any

migraine preventive therapy Exclusion Criteria: 1. History of drug allergy 2. Secondary headaches such as epilepsy or other neurologic disorders 3. Systemic diseases such as asthma, diabetes mellitus , metabolic acidosis , renal stone and hepatic diseases

#### Age

From **5 years** old to **15 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### 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

Bahonare square, Central Bulilding

##### City

Yazd

##### Postal code

#### Approval date

2013-05-22, 1392/03/01

#### Ethics committee reference number

17/1/139746

## Health conditions studied

### 1

#### Description of health condition studied

Migraine headache

#### ICD-10 code

G43.0

#### ICD-10 code description

Migraine without aura [common migraine]

## Primary outcomes

### 1

#### Description

Monthly frequency of headache

#### Timepoint

before and three months after treatment

#### Method of measurement

asking from patient

### 2

#### Description

severity of headache

#### Timepoint

before and three months after treatment

#### Method of measurement

asking from patient

### 3

#### Description

duration of headache

#### Timepoint

before and three months after treatment

#### Method of measurement

asking from patient

### 4

#### Description

Pediatric Migraine Disability score

#### Timepoint

before and three months after treatment

#### Method of measurement

asking from patient

## Secondary outcomes

### 1

#### Description

Side effects

#### Timepoint

monthly until three months after treatment

#### Method of measurement

clinical exam and asking from patients

## Intervention groups

### 1

#### Description

single dose of 1mg/kg/day of amitriptyline at bed time  
for three months

#### Category

Prevention

### 2

#### Description

single dose of 0.3mg/kg/day of melatonin at bed time for three months

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Pediatric neurology clinic of Shahid Sadoughi University of Medical Sciences, Yazd, Iran

**Full name of responsible person**

Dr.Razieh Fallah

**Street address**

**City**

Yazd

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

**Full name of responsible person**

Dr.Fatemah Ezoddini

**Street address**

Bahonar square ,Central buliding 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**

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**

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

**Full name of responsible person**

Dr.razieh Fallah

**Position**

Pediatric neurologist-Associate professor

**Other areas of specialty/work**

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Shahid Sadoughi Hospital, Pediatric Ward

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**Person responsible for scientific inquiries**

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**Position**

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**Other areas of specialty/work**

**Street address**

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**Web page address**

## **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*