Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 melatonine 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 melatonine 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

Street address

Shahid Sadoughi Hospital, Pediatric Ward

City

Yazd

Postal code

Phone

+98 35 1822 4000

Fax

Email

FALLAH@ssu.ac.ir

Web page address

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

Pediatric neurologist-Associate professor

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid Ghandi Blvd Hospital, Pediatric Ward

City

Yazd

Postal code

Phone

+98 35 1822 4000

Fax

Email

FALLAH@ssu.ac.ir

Web page address

Person responsible for updating data

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

Street address

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid Ghandi Blvd

City

Yazd

Postal code

Phone

+98 35 1822 4000

Fax

Email

FALLAH@ssu.ac.ir

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