

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of almond syrup in the treatment of primary sleep disorders in children 6 to 12 years admitted to hospital in the first quarter of 1395 Ziaeian

Protocol summary

Summary

This study is designed to evaluate the effect of almond syrup in the treatment of primary dysomnia in children aged 6 to 12 years. All the children admitted to pediatric clinics who has the inclusion criteria were enrolled in the study. 40 children randomized in two groups and all received 15 ml of a syrup including almond and only preservative substance as placebo. BEARS scoring will be evaluated and mean of scoring will be analyzed in two groups after 3 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021326484N2**
Registration date: **2016-03-09, 1394/12/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-03-09, 1394/12/19

Registrant information

Name

Ghazal Shariat Panahi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

gh-shariatpanahi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Research Grant Scheme

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of almond syrup in the treatment of primary sleep disorders in children 6 to 12 years admitted to hospital in the first quarter of 1395 Ziaeian

Public title

The effect of almond syrup in the treatment of sleep disorders in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: sleep disturbance in the form of dyssomnysia : children 6-12 years Exclusion criteria :any psychiatric underlying disease :cerebral palsy: thyroid disorders : drug use

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

School of Medicine Poor Sina AVE Keshavarz street

City

Tehran

Postal code

1417613151

Approval date

2015-12-07, 1394/09/16

Ethics committee reference number

IR.TUMS.REC.1394.1364

Health conditions studied

1

Description of health condition studied

PRIMARY DYSSOMNIA

ICD-10 code

G47

ICD-10 code description

Sleep disorders

Primary outcomes

1

Description

BEARS questionair score

Timepoint

weekly

Method of measurement

questionair scoring

Secondary outcomes

empty

Intervention groups

1

Description

In this clinical trial study we prescribed 15ml of almond syrup to one group .

Category

Treatment - Drugs

2

Description

In control group we will prescribe 15 ml of a syrup with similar taste and smell that contains only preservative substance

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaian hospital

Full name of responsible person

Ghazal Shariat Panahi MD

Street address

Ziaian hospital Aboozar square Tehran Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences Pardis International Campus

Full name of responsible person

Abbas Shakoori MD

Street address

Poor Sina AVE; Pardis International Campus

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences Pardis International Campus

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

Tehran University of Medical Sciences

Full name of responsible person

Ghazal Shariat Panahi

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Mrjan Noori

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Medical Student

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Person responsible for scientific inquiries

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Ghazal Shariat Panahi

Position

Associate Professor

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Phone

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