

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluate the effectiveness of cyproheptadine on prevention of sleep disorders and appetite caused by the consumption of methylphenidate in children with ADHD and its effects on the efficiency of methyl Fndyt

Protocol summary

Summary

The aim of this study was to evaluate the efficacy of cyproheptadine on prevention of sleep disorders and anorexia in children with ADHD. Study Design: This was a prospective, double-blind study randomized Clinical trial to compare the effect of cyproheptadine with methyl Fenidat insomnia and loss of appetite to reduce the effects caused by the drug deals. The study population consists of children over two years old and suffering from hyperactivity and poor concentration. Inclusion criteria: 1) patient satisfaction, 2) older than 3 years 3) non-use of concomitant medications that have a significant impact on sleep or appetite. Exclusion criteria: 1) the risk of renal failure 2) the risk of cardiovascular diseases 3) the risk of thyroid disease 4) sensitivity to cyproheptadine 5) intolerance side effects. Sample Size: 60. Interventions of the study are methylphenidate plus cyproheptadine and methylphenidate plus placebo and their effects on insomnia and anorexia. Intervention time: 2 months. Study outcomes: prevention of anorexia and insomnia caused by methylphenidate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070623099N1**
Registration date: **2015-10-18, 1394/07/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-18, 1394/07/26

Registrant information

Name

Faeze Kadkhoda Mezerji

Name of organization / entity

Mashhad University of Medical Sciences, School Of Pharmacy

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-04-12, 1394/01/23

Expected recruitment end date

2016-02-23, 1394/12/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the effectiveness of cyproheptadine on prevention of sleep disorders and appetite caused by the consumption of methylphenidate in children with ADHD and its effects on the efficiency of methyl Fndyt

Public title

Cyproheptadine effect on insomnia and loss of appetite caused by methylphenidate in ADHD children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient satisfaction; age older than 3

years old; no use of concomitant medications that have a significant impact on sleep or appetite. Exclusion criteria: the risk of renal failure; the risk of cardiovascular diseases; the risk of thyroid diseases; sensitivity to cyproheptadine; intolerance side effects.

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Mashhad University of Medical Sciences

Street address

College of Pharmacy, Ferdowsi University campus,
Vakil Abad Blvd, Mashhad

City

Mashhad

Postal code

Approval date

2015-06-06, 1394/03/16

Ethics committee reference number

IR.MUMS.REC.1394.183

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

Weight

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

In kilograms and is using the Digital Scale.

2

Description

Height

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

Measured in meters.

3

Description

Growth rate

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

In grams per day

4

Description

Changes in sleep by PSQI scale

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

Using PSQI questionnaire

Secondary outcomes

1

Description

Dry mouth

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

Questionnaire

2

Description

Swelling

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

Questionnaire

3

Description

Sleepiness during the day

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

Questionnaire

4

Description

Gastrointestinal side effects (diarrhea, nausea, vomiting and abdominal pain)

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

Questionnaire

5

Description

Skin reactions

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

Questionnaire

6

Description

Methylphenidate trade name

Timepoint

Baseline; second week; forth week; sixth week; eighth week

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention Groups: cyproheptadine, tablets 4 mg, orally, two half a tablet twice a day for 2 months

Category

Treatment - Drugs

2

Description

In the control group: placebo, tablet, taken orally, once daily for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Sinai Hospital (special clinic)

Full name of responsible person

Dr. Fateme Moharrari

Street address

Sinai Hospital, Horamely street

City

Mashhad

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences, School of Pharmacy

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

E-Campus University of Mashhad-Iran Vakil Abad

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences, School of Pharmacy

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**

Mashhad University of Medical Sciences - School of Pharmacy

Full name of responsible person

Faeze Kakhoda Mezerji

Position

PharmD Student

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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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