

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of Cyproheptadine on weight gain in underweight children ages 2-10 years old.

Protocol summary

Summary

This study is a randomized double blind trial that evaluates effect of Cyproheptadine on weight gain in underweight children. Inclusion criteria include: all children aged 2 to 10 years with a weight below the 50th percentile. Exclusion criteria include: children with underlying organic condition causing growth failure. The sample size was calculated 68 and the study population was children aged 2-10 years with growth failure that referred to gastroenterology clinic at Mousavi Hospital in Zanjan. The patients randomly were divided into two groups. Nutrition education will be reformed into both groups. The first group was given Cyproheptadine syrup with dose 0.1 mg/kg/dose TDS orally for 2 months and the second group was given Placebo with dose 0.1 mg/kg/dose TDS orally for 2 months. The children were assessed every month up to 2 months and the response to treatment (especially weight gain) and adverse effects recorded. All children are re-evaluated two months after cessation of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101318971N3**

Registration date: **2014-10-15, 1393/07/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-15, 1393/07/23

Registrant information

Name

Kambiz Eftekhari

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 7301 3000

Email address

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Recruitment status

Recruitment complete

Funding source

The research department of Zanjan University of Medical Sciences.

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Cyproheptadine on weight gain in underweight children ages 2-10 years old.

Public title

Effect of Cyproheptadine on weight gain in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include: all children aged 2 to 10 years with a weight below the 50th percentile; Children whose parents have given consent to participate in the study. Exclusion criteria include: children with underlying organic condition (gastrointestinal, cardiovascular, respiratory, renal and nervous systems) causing growth failure; inappropriate use of medicines; discourage children from study; did not return for follow-up; occurs

severe disease and side effects of medication.

Age

From **2 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

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**

Zanjan University of Medical Science

Street address

Zanjan

City

Zanjan

Postal code

4513956183

Approval date

2014-08-23, 1393/06/01

Ethics committee reference number

ZUMS.REC.1393.104

Health conditions studied**1****Description of health condition studied**

Growth retardation

ICD-10 code

R64

ICD-10 code description

Cachexia

Primary outcomes**1****Description**

Weight gain

Timepoint

Every month up to 2 months, 2 months after treatment

Method of measurement

Weighing the patient

Secondary outcomes**1****Description**

Increase Height

Timepoint

Every month up to 2 months, 2 months after treatment

Method of measurement

height measurements

2**Description**

Side Effects and complication

Timepoint

Every month up to 2 months, 2 months after treatment

Method of measurement

History and physical examination

Intervention groups**1****Description**

The first group was given Cyproheptadine syrup with dose 0.1 mg/kg/dose TDS orally for 2 months.

Category

Treatment - Drugs

2**Description**

The second group was given Placebo with dose 0.1 mg/kg/dose TDS orally for 2 months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mousavi Hospital

Full name of responsible person

Kambiz Eftekhari

Street address

Pediatric ward, Mousavi Hospital, Ghavazangh Street, Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Science

Full name of responsible person

research department of Zanjan University of Medical Sciences, Dr Aliraza Bighlari

Street address

Zanjan University of Medical Science, Zanjan

City

Zanjan

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

Yes

Title of funding source

Zanjan University of Medical Science

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**

Zanjan University of Medical Science

Full name of responsible person

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Position

Assistant Professor

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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