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

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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
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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