

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of cyproheptadin hydrochloride in treatment of mild to moderate failure to thrive in children who referred to clinics of Shiraz University of Medical Sciences at 1390

Protocol summary

Summary

Eighty patients with mild to moderate failure to thrive (according to Goomez criteria) and normal physical examination without any acute or chronic illness will be referred to laboratory for some paraclinical evaluations: CBC, BUN, venous blood gas, Na, K, Cr, U/A, Stool Exam, LFT, FBS, T4, TSH, TTG(IgA), Total IgA and bone scan. If all are normal, they will be enrolled in our study and their baseline weight (Wt) and height (Ht) will be recorded. Then they will be randomized to 2 equal groups to receive either combination of multivitamins and cyproheptadine (2mg of each/5cc) or only multivitamins (2mg/5cc). The patients will consume these drugs as 0.25 mg/kg/day (divided to twice daily) for 4weeks then their Wt and Ht will be measured at the end of the treatment phase and 4 weeks later. Presumptive complications such as drowsiness or restlessness will be recorded in the clinic according to History and Physical Examination. Then results will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201268827N1**
Registration date: **2012-02-22, 1390/12/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-22, 1390/12/03

Registrant information

Name

Khadijeh Sadat Najib

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4298

Email address

nzahrasan@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-11-06, 1390/08/15

Expected recruitment end date

2012-03-17, 1390/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cyproheptadin hydrochloride in treatment of mild to moderate failure to thrive in children who referred to clinics of Shiraz University of Medical Sciences at 1390

Public title

The effect of cyproheptadine on pediatric growth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children aged between 2 to 5 years old and have mild to moderate failure to thrive. Exclusion criterion: Having organic causes or acute or chronic diseases.

Age

From **2 years** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Shiraz University of Medical Sciences Ethics Committee

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code

Approval date

2011-11-05, 1390/08/14

Ethics committee reference number

CT-90-5795

Health conditions studied

1

Description of health condition studied

Failure to thrive

ICD-10 code

R62.8

ICD-10 code description

Other lack of expected normal physiological development

Primary outcomes

1

Description

Weight

Timepoint

At beginning of study, 1 month after beginning and 1 month after termination of study

Method of measurement

Kilogram

2

Description

Height

Timepoint

At beginning of study, 1 month after beginning and 1 month after termination of study

Method of measurement

Cm

Secondary outcomes

1

Description

Drowsiness

Timepoint

During drug consumption

Method of measurement

History and Physical examination

2

Description

Restlessness

Timepoint

During drug consumption

Method of measurement

History and Physical Examination

Intervention groups

1

Description

Cyproheptadine 0.25 mg/kg/day (twice daily) for 1 month

Category

Treatment - Drugs

2

Description

Multivitamine, 0.25 mg/kg/d(twice daily) for 1 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. GholamReza Haatam

Street address

Zand street, Central structre of SUMS

City

Shiraz

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

Yes

Title of funding source

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Khadijeh Sadat Najib

Position

Assistant Professor of pediatrics

Other areas of specialty/work
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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