Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

The effect of folic acid on homocysteine and plasma insulin levels in weight gain and obesity in children and adolescents

Protocol summary

Summary

To determine the effect of folic acid on homocysteine levels and plasma insulin in children and adolescents with weight gain and obesity, single- center, phase 3 trial 2) Participant: Inclusion criteria: children and adolescents with a body mass index above the eighty-fifth percent for age and sex. Exclusion criteria: obesity due to genetic syndrome, obesity, endocrine disorders such as hypothyroidism and Cushing; children who are on a diet to lose weight, catching any diseases that affect the homocysteine levels such as kidney and liver disease, children who are using supplements 3) Population: 60 patients divide in case and control 4) Interventions : intervention group will be used of folic acid 1 mg daily in first group and the second group received 5 mg daily and the control group do not take drugs 5) Comparison: Six months 6) Outcome: reduction of independent risk factor for cardiovascular

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020116435N1**
Registration date: **2014-05-23, 1393/03/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-23, 1393/03/02

Registrant information

Name

Elham Hashemi

Name of organization / entity

Pediatric endocrinology

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

hashemi_elham@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of folic acid on homocysteine and plasma insulin levels in weight gain and obesity in children and adolescents

Public title

The effect of folic acid on homocysteine and plasma insulin levels in weight gain and obesity in children and adolescents

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: children and adolescents with a body mass index above the eighty-fifth percent for age and sex Exclusion criteria: obesity due to genetic syndrome, obesity, endocrine disorders such as hypothyroidism and Cushing; children who are on a diet to lose weight, catching any diseases that affect the hemocysteine levels such as kidney and liver disease, children who are using supplements

Age
From **5 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)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Shahrekord, Shahrekord University of Medical Sciences
City
Shahrekord
Postal code
Approval date
2012-02-26, 1390/12/07
Ethics committee reference number
12-11-90

Health conditions studied

1

Description of health condition studied
obesity
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Decrease of cardiovascular factor
Timepoint
6 months latter
Method of measurement
sampling

Secondary outcomes

empty

Intervention groups

1

Description
The first group acid folic tablet 1mg receive.
Category
Treatment - Drugs

2

Description
The second group acid folic tablet 5mg daily receive.
Category
Treatment - Drugs

3

Description
Third group served as controls and do not take drugs.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric Endocrinology Clinic of Shahrekord
Full name of responsible person
Elham Hashemi
Street address
Shahrekord , Shahrekord University of Medical Sciences
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shahrekord University of Medical Sciences
Full name of responsible person
Vice chancellor for research of Shahrekord University of Medical Sciences
Street address
Shahrekord, Shahrekord University of Medical Sciences

City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Shahrekord 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Elham Hashemi
Position
Pediatric Endocrinologist, Assistant Professor
Other areas of specialty/work
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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