Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of a high protein diet on weight and height of children with attention deficit hyperactivity disorder receiving Ritalin

Protocol summary

Summary

We aimed to determine effects of a high protein diet on the growth of children with attention deficit hyperactivity disorder receiving Ritalin in a randomized clinical study. Fifty children aged 7 to 12 years with Attention deficit hyper activity disorder (ADHD) referring to a Psychiatric Clinic who receive Ritalin will randomly be assigned to two groups of high protein diet (35% of total calories from protein) Diet or no intervention (control group). In the first visit after obtaining informed consent from parent and child, the child's height and weight will be recorded in standard mode.Then ADHD rating scale, and appetite questionnaire will be completed by parents with the help of the child. Then children will randomly be divided into two groups: high protein group which children will receive a high-protein diet with 35% of total calories from protein by a dietitian based on criteria such as age, height, weight, and size of children. In the control group children will not go on a diet and they only receive Ritalin by psychiatrist. 1 month, 2 months, 3 months, 4 months, 5 months, and 6 months after baseline height and weight and appetite and attention and hyperactivity in children will be assessed. During each month intake of calories and protein in the diet and the diet adherence will be controlled by a 7-day food record.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062116465N4**
Registration date: **2016-01-07, 1394/10/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-01-07, 1394/10/17

Registrant information

Name
Seyed-Ali Mostafavi

Name of organization / entity
Psychiatry Research Center/ Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 5542 2002

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mostafavi_a@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a high protein diet on weight and height of children with attention deficit hyperactivity disorder receiving Ritalin

Public title

Effect of a high protein diet on the growth of hyperactive children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: children 7 to 12 years old; the

diagnosis of ADHD by a psychologist based on diagnostic criteria for DSM V and KSADS interviews; receiving Ritalin by a psychiatrist; signing consent form by parents and oral assent by children Exclusion criteria: dissatisfaction of parent or child; Protein-vitamin supplements or Appetizer medications

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization using a random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Research Deputy of Tehran University of Medical Sciences, Keshavarz Avenue, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-10-10, 1394/07/18

Ethics committee reference number

IR.Tums.REC.1394.905

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity Disorder (ADHD)

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

Height

Timepoint

At baseline and 1 month, 2 month, 3 month, 4 month, 5 month, and 6 month after subjects enrolment

Method of measurement

Measurement will be done using stadiometer in standard situation in cm

2

Description

Weight

Timepoint

At baseline and 1 month, 2 month, 3 month, 4 month, 5 month, and 6 month after subjects enrolment

Method of measurement

Measurement will be done using scale in standard situation in kg

Secondary outcomes

1

Description

Attention deficiency score and Hyperactivity score

Timepoint

At baseline and 1 month, 2 month, 3 month, 4 month, 5 month, and 6 month after subjects enrolment

Method of measurement

ADHD rating scale for children (complited by parents)

Intervention groups

1

Description

Intervention group: In this group a high protein diet with 35% of total calories from protein will be administered by a dietitian plus methylphenidate (Rytalyn- 1 mg per kg weight of the child)

Category

Treatment - Other

2

Description

Control group: In this group no intervention will be done on diet, but children will receive standard treatment with methylphenidate (Rytalyn- 1 mg per kg weight of the child)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Mohammad Reza Mohammadi's Private clinic

Full name of responsible person
Dr. Mohammad Reza Mohammadi

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mrs. Karimi

Street address
Vice chancellor for research, Tehran University of Medical Sciences, Keshavarz Avenue, Tehran

City
Tehran

Grant name
-

Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Seyed-Ali Mostafavi

Position
PhD by research student

Other areas of specialty/work

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Roozbeh Hospital, South Kargar street , Tehran, IRAN

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Tehran University of Medical Sciences, Psychiatry research center

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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