

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Dec 2021

Dietary intervention for treating ADHD, a randomized controlled clinical trial

Protocol summary

Summary

This is a 4 week randomized controlled clinical trial investigating the adjuvant effect of diet recommendation with methylphenidate for treating 80 children with ADHD. Children will be assessed two time including at baseline and the week 4 using a DSM-IV ADHD checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311303930N29**
Registration date: **2013-12-22, 1392/10/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-22, 1392/10/01

Registrant information

Name

Ahmad Ghanizadeh

Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 3070

Email address

ghanizad@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciecnes

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Dietary intervention for treating ADHD, a randomized controlled clinical trial

Public title

Dietary intervention for treating ADHD, a randomized controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children aged between 5 to 18 years old diagnosed with ADHD according to DSM-IV diagnostic criteria. Exclusion criteria: lack of providing written informed consent; serious uncontrolled medical condition such as hypothyroidism, serious interaction of recommended diet with a medical condition or methylphenidate.

Age

From **5 years** old to **18 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)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code

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Approval date

2013-09-22, 1392/06/31

Ethics committee reference number

CP-P-92-6001

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

Hyperkinetic disorders- Attention deficit Hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Hyperkinetic disorders

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

ADHD Rating Scale

Timepoint

baseline and week 4

Method of measurement

Interview

Secondary outcomes

empty

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

recommendation to reduce sugar intake for one month

Category

Behavior

2**Description**

Control - without diet recommendation

Category

N/A

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

Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences

Full name of responsible person

Ahmad Ghanizadeh

Street address

Hafez Hospital

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical sciences

Full name of responsible person

Gholam Reza Hatam

Street address

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

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

Behzad Hadad

Position

Medicine Student

Other areas of specialty/work**Street address**

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Ahmad Ghanizadeh

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Professor of Psychiatry

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Person responsible for updating data

Contact

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