Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Vitamin D for treating autism, a controlled clinical trial

Protocol summary

Summary

This non-randomized 8-week controlled clinical trial examines the effect of vitamin D for treating children with autism and vitamin serum level less than 25ng/ml. There are two groups. Each group incudes 15 patients. One group will receive vitamin D. The other group will receive vitamin D plus risperidone. Aberrant Behavior checklist is used to measure the clinical symptoms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405273930N34**
Registration date: **2014-10-17, 1393/07/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-17, 1393/07/25

Registrant information

Name
Ahmad Ghanizadeh
Name of organization / entity
Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences
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Iran (Islamic Republic of)
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+98 71 1627 3070
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ghanizad@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sceicnes

Expected recruitment start date

2014-08-07, 1393/05/16

Expected recruitment end date

2015-08-07, 1394/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Vitamin D for treating autism, a controlled clinical trial

Public title

Vitamin D for treating autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Autism according to DSM-IV diagnostic criteria; aged 3 to 18 years old; and serum level of vitamin D less than 25 ng/mL. Exclusion Criteria: primary diagnosis of a psychotic disorder; active substance abuse or dependence; history of allergy to vitamin D; and unstable medical condition.

Age

From **3 years** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not 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 Sciecnes
Street address
Shiraz University of Medical Sceinces
City
shiraz
Postal code
Approval date
2014-08-03, 1393/05/12
Ethics committee reference number
92-01-34-6787

Health conditions studied

1

Description of health condition studied
autism spectrum disorder
ICD-10 code
F84.0
ICD-10 code description
Childhood autism

Primary outcomes

1

Description
Clinical behavioral symptoms
Timepoint
Every 4 weeks
Method of measurement
Abbrant Behavior Checklist

Secondary outcomes

empty

Intervention groups

1

Description
An intramuscular vitamin D 300,000 IU repeated one week later plus risperidone (0.5 to 3 mg/day)
Category
Treatment - Drugs

2

Description
control group will receive vitamin D
Category
Treatment - Drugs

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
Vice chancellor for research, Shiraz University of Medical sciences
Full name of responsible person
Basi Hasemi
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
Vice chancellor for research, 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

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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