Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy of A Gluten-Free Diet on Behavioral Of Autistic Children Without Gastrointestinal Disorders

Protocol summary

Summary

This randomized clinical trial with a control group has been done to determine the effect of gluten-free diet on behavioral symptoms of autistic children without gastrointestinal disorders. 120 children with autism located in autism centers of Gilan and Mazandaran were evaluated. Autism Spectrum Disorders and age range of 3-15 years old were the inclusion criteria and not having the symptoms of autism and unwillingness to participate in the study were exclusion criteria of the study. In the clinical interview, questionnaires of Gilliam Autism Rating (GARS1) to assess the severity of symptoms of autism and Gastrointestinal Symptom Rating Scale (GSRS) to screening for autistic children with gastrointestinal disorders, was completed by parents. Then, 29 screened children, were randomly divided into two intervention and control groups. In the intervention group, gluten-free diet (gluten-free cereals about 200 grams per day) and in the control group around 200 grams of cereals containing gluten have been included for 3 months. At the end, GARS1 was repeated in both groups and the questionnaire were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082215339N2**
Registration date: **2016-09-12, 1395/06/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-12, 1395/06/22

Registrant information

Name

Ali Akbar Esmaeliranjbar

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1211 1613

Email address

esmaeli@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

personal

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-01-05, 1390/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of A Gluten-Free Diet on Behavioral Of Autistic Children Without Gastrointestinal Disorders

Public title

Efficacy of A Gluten-Free Diet on Behavioral Of Autistic Children Without Gastrointestinal Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: autism Exclusion criteria: not having the symptoms of autism and unwillingness to participate in research

Age

From **3 years** old to **15 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **29**
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
Ethics committee of Kerman University of Medical Sciences
Street address
No. 24, Ebnesina St, Jahad Blvd.,Somayeh Cross.
City
Kerman
Postal code
7619813159
Approval date
2013-08-27, 1392/06/05
Ethics committee reference number
92/220/ل‌ک

Health conditions studied

1

Description of health condition studied
Childhood Autism
ICD-10 code
F84.0
ICD-10 code description
Childhood Autism

Primary outcomes

1

Description
Symptoms of Autism
Timepoint
Before and three months after intervention.
Method of measurement
GARS Questionnaire and Visual Scale of Behaviors

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Gluten-free diet(bread, biscuits, pasta, cakes and a variety of cookies without gluten), about 200 grams per day for 3 months
Category
Lifestyle

2

Description
Control group:Gluten diet(bread, biscuits, pasta, cakes and a variety of cookies with gluten), about 200 grams per day for 3 months
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid Ayandeh
Full name of responsible person
Fatemeh Rabiae
Street address
No. 14, Shabani 2nd Alley, Khoshkalam Alley, Gas square toward Tooshiba, Rasht.
City
Rasht

2

Recruitment center
Name of recruitment center
Besharat
Full name of responsible person
Mahin Poor Mohamad
Street address
No. 23, Amoo blind alley, next to the Guilan sport, Imam St., Shahrdari square, Rasht.
City
Rasht

3

Recruitment center
Name of recruitment center
Mansoor
Full name of responsible person
Mahin Dokht Azarney
Street address

No. 9, across Hajbaba bakery, Ershad alley, Ansari Blvd.

City

Rasht

4

Recruitment center

Name of recruitment center

ShadPooya

Full name of responsible person

Sheyda Khanzadeh

Street address

No. 12, Shahid Esmaeil Nezhad Moghadam Alley, Vahedi St., Anzalee.

City

Anzalee

5

Recruitment center

Name of recruitment center

Afra

Full name of responsible person

Elham Akbari

Street address

No. 55, Mirzaye Shirazi Alley, Jomhoori St.,

City

Tonekabon.

6

Recruitment center

Name of recruitment center

Shahid Babaee

Full name of responsible person

Mrs Balassi

Street address

No.45, Opposit Krym Abad Park,

City

Tonekabon.

7

Recruitment center

Name of recruitment center

Shahid Baraghi

Full name of responsible person

Hamideh Ghanbari

Street address

No. 18, Baghmeli St.

City

Ramsar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Islamic Azad University of Tonekabon

Full name of responsible person

Hosein Ali Mashayekhi

Street address

Islamic Azad University - Tonekabon Branch, Vali Abad,

City

Tonekabon

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 Islamic Azad University of Tonekabon

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

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Amini Ranjbar

Position

Master of Clinical Psychology

Other areas of specialty/work

Street address

Kerman University of Medical Sciences, International Campus. Haft Bagh.

City

Kerman

Postal code

7614745969

Phone

+98 34 3223 7337

Fax

+98 34 3211 1613

Email

aminiranjbar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Amini Ranjbar

Position

Master of Clinical Psychology

Other areas of specialty/work

Street address
Kerman University of Medical Sciences, International Campus. Haft Bagh. Kerman
City
Kerman
Postal code
7614745969
Phone
+98 34 3223 7337
Fax
+98 34 3211 1613
Email
aminiranjbar@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Health Technology Incubator Center, Vice chancellor for research, Kerman University of Medical Scien
Full name of responsible person
Ali Akbar Esmaeili
Position
Director of the Center
Other areas of specialty/work
Street address
No. 3, between Farhangian and Keshavarz crosses, Jomhoori Blvd
City
Kerman
Postal code
7614745969
Phone
+98 34 3211 4535
Fax
+98 34 3211 1613
Email
esmaeliranjbar@yahoo.com
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