

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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
92/220/15

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., Shahr-dari 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 Esmail 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.

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Recruitment center

Name of recruitment center

Shahid Babaei

Full name of responsible person

Mrs Balassi

Street address

No.45, Opposit Krym Abad Park,

City
Tonekabon.

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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

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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,

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