

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Pidrolax With or Without A Gluten-Free Diet on Gastrointestinal Symptoms and Behavioral Of Autistic Children with Gastrointestinal Disorders

Protocol summary

2016-09-18, 1395/06/28

Summary

This randomized clinical trial with a control group has been done to compare the effects of Pidrolax with or without the gluten-free diet on intensity of autism symptoms and gastrointestinal disorders in children with autism. 120 children with autism located in Autism Centers of Guilan 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, 65 screened children, were randomly divided into two intervention and control groups. In both groups Pidrolax powder at a dose of 25-12 grams per day for a period of time (no symptoms of constipation), in the intervention group also gluten-free diet (about 200 grams of wheat gluten) and the control group of about 200 grams of cereals containing gluten, was used for 3 months. At the end, two tests were repeated and the questionnaires were evaluated

Registrant information

Name

Ali Akbar Esmaeliranjbar

Name of organization / entity

Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

private

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 Pidrolax With or Without A Gluten-Free Diet on Gastrointestinal Symptoms and Behavioral Of Autistic Children with Gastrointestinal Disorders

Public title

Pidrolax With or Without A Gluten-Free Diet on Gastrointestinal Symptoms and Behavioral Of Autistic Children

Purpose

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110915339N1**

Registration date: **2016-09-18, 1395/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

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: **65**

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, Jihad Blvd., Somayeh Cross.

City

Kerman

Postal code

7619813159

Approval date

2013-08-27, 1392/06/05

Ethics committee reference number

92/220/k

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

2

Description

Gastrointestinal symptoms

Timepoint

Before and three months after intervention.

Method of measurement

GSRS Questionnaire and Visual Scale of Pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pidrolax powder at a dose of 25-10 grams per day for a period of time, for 3 months. Gluten-free diet(bread, biscuits, pasta, cakes and a variety of cookies without gluten). about 200 grams per day for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Pidrolax powder at a dose of 25-10 grams per day for a period of time, for 3 months. Gluten diet(bread, biscuits, pasta, cakes and a variety of cookies with gluten,normal diet), about 200 grams per day for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Ayandeh

Full name of responsible person

Fatemeh Rabiaie

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 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

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, Tonekabon.

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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Health Technology Incubator Center, Vice chancellor for research, Kerman University of Medical Sciences
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Director of the Center
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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