Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

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

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

2016-09-18, 1395/06/28

Registrant information

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Name of organization / entity
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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

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, Jahad 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 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
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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
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6

Recruitment center
Name of recruitment center
Shahid Babaee
Full name of responsible person
Mrs Balassi
Street address
No.45, Opposit Krym Abad Park
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7

Recruitment center
Name of recruitment center
Shahid Baraghi
Full name of responsible person
Hamideh Ghanbari
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No. 18, Baghmeli St.
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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

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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