

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of Gluten-free diet on gastrointestinal symptoms and disease severity of Autistic children

Protocol summary

Study aim

The effect of Gluten-free diet on gastrointestinal symptoms and disease severity of Autistic children

Design

Double-blinded randomized clinical trial on 80 patients with parallel groups

Settings and conduct

All patients with autism referred to Sheikh Al-Rais Clinic and Tabriz Children's Hospital will be included in the study. The diagnosis of autism is made by neurologists and psychologists and the M-CHAT rf questionnaire will be completed for patients. The project nurse who divides the patients and analyzes the study data were blinded to the intervention groups.

Participants/Inclusion and exclusion criteria

Patients with autism spectrum disorders in the patient, the presence of gastrointestinal symptoms such as abdominal pain, vomiting, constipation and diarrhea, parental consent and adherence to the treatment regimen and the age of two to sixteen years will be included in the study. Patients will be excluded from the study if their parents do not agree to follow a gluten-free diet and have other known gastrointestinal or neurological problems.

Intervention groups

The intervention group will receive a gluten-free diet at a normal meal and the control group will receive a normal diet.

Main outcome variables

Severity of autism, abdominal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200115046137N2**

Registration date: **2021-06-07, 1400/03/17**

Registration timing: **prospective**

Last update: **2021-06-07, 1400/03/17**

Update count: **0**

Registration date

2021-06-07, 1400/03/17

Registrant information

Name

Shahram Sadeghvand

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Gluten-free diet on gastrointestinal symptoms and disease severity of Autistic children

Public title

Gluten-free diet in Autistic children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of autism spectrum disorders in the patient

Gastrointestinal symptoms such as heartburn, vomiting, constipation and diarrhea Parental satisfaction and adherence to the treatment regimen Age two to sixteen

Exclusion criteria:
Parents' dissatisfaction with following a gluten-free diet
Having other known gastrointestinal or neurological problems

Age
From **2 years** old to **16 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be using sealed envelopes, of which 80 envelopes will be selected in total and will be divided into two groups of 40, including groups A and B. Envelopes will be selected by the neurology ward's nurse who is blind to the study groups. Group A will be the intervention group, group B will be the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The project nurse who divides the patients and analyzes the study data in relation to the blind intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Square

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2021-04-26, 1400/02/06

Ethics committee reference number
IR.TBZMED.REC.1400.089

Health conditions studied

1

Description of health condition studied
Autism

ICD-10 code
F84.0

ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
Autism severity

Timepoint
Initiation of the study, 3 months after the intervention

Method of measurement
M-Chat-RF questionnaire

2

Description
Abdominal pain

Timepoint
Initiation of the study, 3 months after the intervention

Method of measurement
Clinical examination and visual analogue scale

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: They will receive a gluten-free diet at normal meals.

Category
Treatment - Other

2

Description
Control group: They will receive a normal routine diet.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Dr. Mir Hadi Mousavi

Street address

Tabriz Children Hospital, Sheshgelan Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

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Vice chancellor for research, Tabriz University of medical sciences, Daneshgah square

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Shahram Sadeghvand

Position

Pediatric neurologist

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Children Hospital, Seshghelaan St., Seggat ol Eslam Ave.

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long

Access to study data after publication of the result is available in the journal.

To whom data/document is available

Anyone interested in using the data can access the study data.

Under which criteria data/document could be used

Study data can be used for comparison with other results.

From where data/document is obtainable

Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document

The request will be sent by email to person responsible for scientific or public inquiries.

Comments