Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of ketogenic diet on function autistic children

Protocol summary

Study aim
The purpose is to investigate the effectiveness of the prescribed treatment regimen in the performance of children with autism so that treatment and support services can be started as soon as possible and improve the cognitive and developmental process of these children as much as possible. became

Design
Clinical trial on the intervention group (before and after the diet), without parallel group, not blinded, not randomized, on 30 patients.

Settings and conduct
Application of ketogenic diet to children with autism referring to neurology clinics of Azari Mardani Children's Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Children with autism • Age 3 to 10 years • Proper training of parents to start and continue the diet and urine ketone measurement • Informed consent of the patient's parents for the child's participation in the study Exclusion criteria: • History of clinical seizures in history • Presence of epileptiform waves in EEG

Intervention groups
Children treated with a ketogenic diet (before and after the «ketogenic diet)

Main outcome variables
Cognitive and functional evaluation before and after applying the ketogenic diet

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131012014988N9**
Registration date: **2024-01-05, 1402/10/15**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-05, 1402/10/15**
Update count: **0**

Registration date
2024-01-05, 1402/10/15

Registrant information

Name
Mohammad Barzegar

Name of organization / entity
Pediatric Health Research Center,Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-12-21, 1403/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of ketogenic diet on function autistic children

Public title
The effect of ketogenic diet on autism

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 3 to 10 years The complaint of speech delay and lack of social communication according to the points

obtained: 20-8 with high risk of autism, 3-7 with moderate risk for autism in the completed Modified Checklist for Autism in Toddlers (M-CHAT) questionnaire. The child's parents or caregivers have the appropriate training to start, continue the diet, measure urine ketones, and record information in the relevant form, and the informed consent of the patient's parents for the child's participation in the study; is.

Exclusion criteria:

History of clinical seizures in history Presence of epileptiform waves in EEG

Age

From **3 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Golgasht Ave, Medicine faculty

City

Tabriz

Province

East Azarbaijan

Postal code

5157610144

Approval date

2023-12-04, 1402/09/13

Ethics committee reference number

IR.TBZMED.REC.1402.648

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Evaluation of cognitive function

Timepoint

Before starting the diet and 3 months later

Method of measurement

Evaluation and comparison of Autism Treatment Evaluation Checklist (ATEC) score in children with autism before and after the diet

Secondary outcomes

1

Description

Evaluation and comparison of beta-hydroxybutyrate levels

Timepoint

Before starting the diet and 3 months later

Method of measurement

Serum levels of beta-hydroxybutyrate before and after applying the ketogenic diet will be assessed by a biochemistry autoanalyzer and a commercial kit using a photometric method.

Intervention groups

1

Description

In this study, children with autism will be treated with a ketogenic diet. The classic ketogenic diet is high in fat, low in carbohydrates, and moderate in protein, adjusted to a ratio of 4:1 or 3:1 (protein and carbohydrate:fat). This diet mimics the state of fasting and changes the metabolism to use fats as the main source of energy, and the catabolism of fatty acids in the liver produces ketone bodies, which causes urinary ketosis. Before starting the regimen, routine tests will be performed and serum beta-hydroxybutyrate levels will be assessed. Also, ATEC questionnaire will be filled for patients. Then the ketogenic diet will be applied to the patients. After four months, the tests will be repeated and the ATEC questionnaire will be filled.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Zahra Mardani Azari Children Hospital

Full name of responsible person
Dr. Mohammad Barzegar

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Mardani Azari St. Khavaran Town.Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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. Mohammad Barzegar

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatric Nourologist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available