

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3526 2265

###### Email address

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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

**Street address**

Mardani Azari St. Khavaran Town.Tabriz

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Parviz Shahabi

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Golgash St. Daneshgah St. Tabriz

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research-vice@tbzmed.ac.ir

**Web page address**

<https://researchvice.tbzmed.ac.ir/>

**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 Neurologist

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**

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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