Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical Trials Of Effects Of Carnosine Supplementation On Serotonin, Glutamate And Disease Severity In Children With Autism Disorder

Protocol summary

Summary

Object of study: investigation of the effect of Carnosine supplementation on serotonin and glutamate levels and autism severity in children with autism disorder. Study design: Random, double blind, Control with Placebo. Study population: Children with autism will be randomly(Blocking) divided into 2 intervention groups:1. Carnosine receiver group (a 500 mg capsule with lunch) 2. Placebo receiver group (a Placebo capsule containing 500 mg starch with lunch). The main inclusion criteria: diagnosis of Autism by psychologist; age between 6-12 years old; unchanged method of medical treatment since two months before intervention and through out follow up time; not receiving other supplements; mental retardation. The main exclusion criteria: consumption of any types of Chelator drugs in study duration; following of special diet; neurological diseases like epilepsy, Cerebral Palsy and...; all types of metabolic disorders; medical treatment method alteration during study period; adherence of supplemen less than 75 percent. Sample size: 50 persons (2 groups of 25 people). (B) Intervention or interventions studied: two group: 1. Carnosine receiver group 2. Placebo receiver group (c) intervention time: 8 weeks. (D) The primary outcome of the study: The impact of Carnosine supplementation on autism severity, sleep and gastrointestinal disorder, plasma serotonin and glutamate levels and dietary intake . Secondary outcomes of the study: The impact of supplement usage on activity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061711689N4**
Registration date: **2016-12-02, 1395/09/12**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-12-02, 1395/09/12

Registrant information

Name
Sorayya Kheirouri
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1335 7580
Email address
kheirouris@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Tabriz University Of Medical Science

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trials Of Effects Of Carnosine Supplementation On Serotonin, Glutamate And Disease Severity In Children With Autism Disorder

Public title

Effects Of Carnosine On Autism

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of Autism by psychologist; age between 6 to 12 years old; unchanged method of medical treatment since two months before intervention and through out follow up time; not receiving other supplements; mental retardation. Exclusion criteria: consumption of any types of Chelator drugs in study duration; following of special diet; neurological diseases like epilepsy, Cerebral Palsy and...; all types of metabolic disorders; medical treatment method alteration during study period; adherence of supplement less than 75 percent.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Comittee Of Tabriz University Of Medical Science

Street address

Golgasht Ave,Attar Ave,Nutrition Faculty

City

Tabriz

Postal code

Approval date

2016-03-16, 1394/12/26

Ethics committee reference number

IR.TBZMED.REC.1395.105

Health conditions studied

1

Description of health condition studied

Autism Disorder

ICD-10 code

f84.0

ICD-10 code description

autism disorders

Primary outcomes

1

Description

serotonin

Timepoint

at Beginning and eighth week of the study

Method of measurement

ELISA

2

Description

glutamat

Timepoint

at Beginning and eighth week of the study

Method of measurement

HPLC

3

Description

Autism disorder severity

Timepoint

At Beginning and eighth week of the study

Method of measurement

GARS questionnaire

4

Description

Gastrointestinal disorders

Timepoint

At Beginning and eighth week of the study

Method of measurement

ROME3 questionnaire

5

Description

Sleep disorders

Timepoint

At Beginning and eighth week of the study

Method of measurement

CSHQ questionnaire

6

Description

food intake

Timepoint

At Beginning and fourth week and eighth week of the study

Method of measurement
3 days food intake

Secondary outcomes

1

Description
phisical activity
Timepoint
At Beginning and eighth week of the study
Method of measurement
international phisical activity questionnaire

Intervention groups

1

Description
Intervention group: Intake of Carnosine 500 mg capsule once a day with lunch, for 8 weeks.
Category
Other

2

Description
Placebo group: Intake of Placebo capsule containing 500 mg of starch, which is similar to Carnosine supplement in terms of dosage, color and size, once a day for 8 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Arad Rehabilitation Center
Full name of responsible person
MehrAsa Alizadeh
Street address
No.32, Mahboubi 12, Mahboubi Ave, Pasdaran Ave
City
Babolsar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy Of Research And Technology Of Tabriz University Of Medical Science, Nutritional Science Resea
Full name of responsible person
Mohammad Reza Rashidi
Street address
Deputy Of Research And Technology, 3th Floor, Central Bulilding 2,Tabriz University Of Medical Sciences, Golgasht Ave,
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy Of Research And Technology Of Tabriz University Of Medical Science, Nutritional Science Resea
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
Nutrition Sciences Faculty, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Sorayya kheirouri
Position
PhD Of Nutrition- Associate Professor
Other areas of specialty/work
Street address
Nutrition Sciences Faculty, Tabriz University of Medical Sciences, Attar Neyshabori Ave, Golgasht Ave
City
Tabriz
Postal code
5166614711
Phone
+98 41 3335 7580
Fax
Email
kheirouris@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Nutrition Sciences Faculty, Tabriz University Of Medical Sciences
Full name of responsible person
Dr. Sorayya kheirouri
Position
PhD of nutrition- Associate Professor
Other areas of specialty/work
Street address
Nutrition Sciences Faculty, Attar Neyshabori Ave,

Golgasht Ave
City
Tabriz
Postal code
5166614711
Phone
+98 41 3335 7580
Fax
Email
kheirouris@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
MehrAsa Alizadeh
Position
MSc Student Of Health Sciences In Nutrition
Other areas of specialty/work
Street address
Nutrition Faculty, Attar ave, Golgasht Ave
City
Tabriz
Postal code
Phone
+98 11 3233 8456
Fax
Email
Asa.alizade@yahoo.com
Web page address

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