

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 supplement 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

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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 Committee 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

physical activity

Timepoint

At Beginning and eighth week of the study

Method of measurement

international physical 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

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Person responsible for scientific inquiries

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PhD of nutrition- Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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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