Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of carnosine supplementation on plasma melatonin, oxytocin and advanced glycation and precursors of lipoxidation end products levels and sleep and gasterointestinal disorders in children with autism disorder

Protocol summary

Summary

Object of study: investigation of the effect of Carnosine supplementation on plasma melatonin, oxytocin and advanced glycation and precursors of lipoxidation end products levels and sleep and gastrointestinal disorders in children with autism disorder. Study design: Random, double blind, Control with Placebo. Study population: Children with autism will be randomly divided into 2 intervention groups:1. Carnosine recipient group (a 500 mg capsule with lunch) 2. Placebo recipient group (a Placebo capsule containing 500 mg starch with lunch). The main inclusion criteria: diagnosis of Autism by psychologist; age between 4-16 years old; tend to cooperation; 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: any type of Chelator drugs consumption in study duration; following special diets; neurological diseases like epilepsy, Cerebral Palsy and...; all types of metabolic disorders; medical treatment method alteration during study period; disinclination to start or to continue cooperation; acceptance rate less than 75 percent. Sample size: 50 persons (2 groups of 25 people). (B) Intervention or interventions studied: two group: 1. Carnosine recipient group 2. Placebo recipient group (c) intervention time: 8 weeks. (D) The primary outcome of the study: The impact of Carnosine supplementation on sleep and gastrointestinal disorders, plasma Melatonin, Oxytocin and advanced glycation and precursors of lipoxidation end products levels and autism severity. Secondary outcomes of the study: The impact of supplement usage on anthropometric indices and hyperactivity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061711689N5**
Registration date: **2016-07-08, 1395/04/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-08, 1395/04/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

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
Effects of carnosine supplementation on plasma melatonin, oxytocin and advanced glycation and precursors of lipoxidation end products levels and sleep and gasterointestinal disorders in children with autism disorder

Public title
Effects of carnosine supplementation on autism disorder
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: diagnosis of Autism by psychologist; age between 4-16 years old; tend to cooperation; unchanged method of medical treatment since two months before intervention and through out follow up time; not receiving other supplements; mental retardation. Exclusion criteria: any type of Chelator drugs consumption in study duration; following special diets; neurological diseases like epilepsy, Cerebral Palsy and...; all types of metabolic disorders; medical treatment method alteration during study period; disinclination to start or to continue cooperation; acceptance rate less than 75 percent.
Age
From **4 years** old to **16 years** old
Gender
Both

Phase
2
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
Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, East Azerbaijan
City
Tabriz
Postal code
Approval date
2016-03-07, 1394/12/17
Ethics committee reference number
IR.TBZMED.REC.1395.106

Health conditions studied

1

Description of health condition studied
Autism disorder
ICD-10 code
F84.0
ICD-10 code description
Childhood autism

Primary outcomes

1

Description
Sleep disorders
Timepoint
Beginning and eighth week of the study
Method of measurement
CSHQ questionnaire

2

Description
Gastrointestinal disorders
Timepoint
Beginning and eighth week of the study
Method of measurement
ROME3 questionnaire

3

Description
Plasma levels of Melatonin
Timepoint
Beginning and eighth week of the study
Method of measurement
ELISA

4

Description
Plasma levels of Oxytocin
Timepoint
Beginning and eighth week of the study
Method of measurement
ELISA

5

Description

Autism disorder severity
Timepoint
Beginning and eighth week of the study
Method of measurement
GARS questionnaire

Secondary outcomes

1

Description
Height
Timepoint
Beginning and eighth week of the study
Method of measurement
Seca stadiometer

2

Description
weight
Timepoint
Beginning and eighth week of the study
Method of measurement
Seca scale

3

Description
Body Mass Index
Timepoint
Beginning and eighth week of the study
Method of measurement
(weight/(Height)2)

4

Description
Hyperactivity
Timepoint
Beginning and eighth week of the study
Method of measurement
Conners questionnaire

Intervention groups

1

Description
Intervention group: Intake of Carnosine 500 mg capsule once a day with lunch, prepared by Nova nutritions, 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
Psychiatry clinic
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research and technology of Tabriz university of medical science
Full name of responsible person
Mohammad Reza Rashidi
Street address
3th floor, Central bulilding, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz
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
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 and Food Sciences Faculty, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Sorayya kheirouri
Position
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Other areas of specialty/work
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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