

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effects 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

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

Name

Sorayya Kheirouri

Name of organization / entity

Tabriz University of Medical Sciences

Country

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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 gastrointestinal 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

PhD of nutrition- Associate Professor

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