# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Effect of coenzyme Q10 versus placebo on improving symptoms of autism spectrum disorder: a double-blind randomized clinical trial

## Protocol summary

**Study aim**
To assess the effect of coenzyme Q10 versus placebo on improving symptoms of autism spectrum disorder
**Design**
This is a double-blind randomized clinical trial, phase II, in which 50 eligible patients will be randomly assigned to the intervention and control groups
**Settings and conduct**
The eligible patients with autism spectrum disorder referring to Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician will examine the patients will be aware of the intervention.
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age of 6 to 12 years, Autism spectrum disorder Exclusion criteria: Taking antioxidant and anti-inflammatory drugs over the past month, Drug intolerance
**Intervention groups**
Intervention group: Coenzyme Q10 capsule 100 mg (manufactured by Hakiman Teb Pharmaceutical Company) once daily for 8 weeks Control group: Placebo capsule (manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) once daily for 8 weeks
**Main outcome variables**
Primary outcome: Symptoms of autism

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20120215009014N330**
Registration date: **2020-01-06, 1398/10/16**
Registration timing: **prospective**
Last update: **2020-01-06, 1398/10/16**
Update count: **0**
**Registration date**
2020-01-06, 1398/10/16

**Registrant information**
**Name**
Jalal Poorolajal
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Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2020-01-21, 1398/11/01
**Expected recruitment end date**
2020-05-20, 1399/02/31
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effect of coenzyme Q10 versus placebo on improving symptoms of autism spectrum disorder: a double-blind randomized clinical trial

**Public title**
Effect of coenzyme Q10 versus placebo on improving symptoms of autism spectrum disorder
**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age of 6 to 12 years, Autism spectrum disorder

**Exclusion criteria:**

Taking antioxidant and anti-inflammatory drugs over the past month, Drug intolerance

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

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**Approval date**

2019-10-26, 1398/08/04

**Ethics committee reference number**

IR.UMSHA.REC.1398.622

## 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**

Symptoms of autism

**Timepoint**

Before the intervention and 8 weeks after that

**Method of measurement**

By using the standard questionnaire of Childhood Autism Rating Scale (CARS)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: Coenzyme Q10 capsule 100 mg (manufactured by Hakiman Teb Pharmaceutical Company) once daily for 8 weeks

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Placebo capsule (manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) once daily for 8 weeks

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Sina Hospital in Hamadan city
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Hamedan 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**

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## Person responsible for updating data

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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