Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of zinc gluconate supplementation on nutritional status, exercise performance and some of the biochemical parameters in Boccia paralympic athletes

Protocol summary

Study aim

Determining the effect of zinc gluconate supplementation on nutritional status, athletic performance, and some biochemical parameters in Paralympic Boccia athletes

Design

a double-blind, randomized controlled clinical trial that will be conducted on 24boccia athletes in Tabriz.

Settings and conduct

This study will be conducted on boccia athletes in Tabriz. Eligible individuals will complete a written consent form and general information. Individuals will be randomly divided into two groups using RASS software. Anthropometric measurements including weight, height, BMI calculation, arm circumference and skinfold fat thickness of the triceps muscle area will be taken at the beginning and end of the study, and weighing with and without a wheelchair on a scale will be used to determine weight. Questionnaires on general characteristics, appetite, and a three-day food record will be completed. Also, a 5-cc blood sample will be taken up to 24 hours after the training session, to determine serum levels of biochemical indicators. also Evaluations related to sports performance will be taken.

Participants/Inclusion and exclusion criteria

Inclusion criteria included athletes with physical and motor disabilities; age between 18 and 40 years; at least 2 years of training experience and willingness to participate in the study. Exclusion criteria: less than 2 years of training experience; swallowing disorders; chronic diseases such as diabetes, lipid disorders, liver failure, etc.; use of epilepsy drugs and corticosteroids; severe allergic reaction to the supplement or placebo; use of smoking, alcohol, and hookah.

Intervention groups

The intervention group will take a daily supplement of 30 mg zinc gluconate and the control group will take the same dose, volume, shape, and taste of a maltodextrin placebo, preferably with a snack other than milk, for 8 weeks.

Main outcome variables

Nutritional status, athletic performance, and some biochemical parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250506065624N2**
Registration date: **2025-05-24, 1404/03/03**
Registration timing: **prospective**

Last update: **2025-05-24, 1404/03/03**
Update count: **0**

Registration date

2025-05-24, 1404/03/03

Registrant information

Name

Vahideh Ebrahimzadeh Attari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3335 7581

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-26, 1404/03/05

Expected recruitment end date

2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc gluconate supplementation on nutritional status, exercise performance and some of the biochemical parameters in Boccia paralympic athletes

Public title

Effect of zinc gluconate supplementation on nutritional status, exercise performance and some of the biochemical parameters in Boccia paralympic athletes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Athletes with physical and mobility disabilities Age between 18 years and 40 years At least two years of practice experience Willing to participate in the study

Exclusion criteria:

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to either the intervention or placebo group using simple randomization through the Random Allocation Software (RASS). This software will automatically generate a random allocation sequence in which each participant will have an equal probability (50%) of being assigned to one of the two groups. In this method, the allocation of each individual will be entirely independent of others, and the order of participant enrollment will not influence the randomization process. To ensure allocation concealment, the random codes generated by the software will be placed in sealed, opaque, and sequentially numbered envelopes, to be opened in the order of participant enrollment. These codes will only indicate group designation (Group A or Group B), and both the investigators and participants will remain blinded to the actual content of the intervention (supplement or placebo) until data collection is complete. This procedure is intended to minimize allocation bias and enhance the internal validity of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in order to minimize bias and enhance the validity of the results, a double-blind design will be employed, whereby neither the participants nor the principal investigator will be aware of the group assignments (intervention or control). The blinding process will be implemented according to the following steps: First, eligible participants will be randomly assigned to either the intervention or control group. To maintain impartiality, the allocation will be performed by an independent individual who will not be involved in data collection or data analysis. The intervention supplement and the placebo will be identical in appearance, color, size, odor, and packaging, and will be prepared by a pharmaceutical company. Each participant will receive the assigned product based on numerical coding (e.g., A and B). These codes will remain confidential with the individual responsible for blinding until the completion of data analysis. All participants will receive standardized instructions on how to consume the supplement, without any knowledge of their group assignment. Furthermore, the researcher responsible for data collection and analysis will remain blinded to the group allocations throughout the study. After the data collection phase is complete, the codes will be unblinded and the data will be analyzed accordingly. The use of this approach is expected to minimize the risk of both conscious and unconscious bias on the part of the researcher and the participants, thereby improving the internal validity of the study.

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 Sciences

Street address

Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2025-04-14, 1404/01/25

Ethics committee reference number

IR.TBZMED.REC.1404.060

Health conditions studied

1

Description of health condition studied
Boccia athletes with cerebral palsy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Nutritional status (energy intake, macronutrients, micronutrients, anthropometric indices, appetite)
Timepoint
Beginning and end of the study
Method of measurement
Anthropometric measurements including weight, height, BMI calculation, determination of arm circumference and thickness of skinfold fat of the triceps muscle area using calipers will be performed by the researcher at the beginning and end of the study. Considering the severe physical and motor disability of the athletes, weighing with and without a wheelchair on a scale with an accuracy of 0.1 kg will be used to determine weight. A tape measure with an accuracy of 0.1 cm will be used to measure height and alternative methods of determining height such as ulna or determining the length of the lower leg. Initially, the study participants will use a 5-item questionnaire based on a Likert scale (answers 0 to 10) to determine appetite, the validity and reliability of which have been previously determined, and a 3-day food record will be performed to determine calorie and nutrient intake.

2

Description
Athletic performance (throwing distance, muscle strength)
Timepoint
Beginning and end of the study
Method of measurement
At the beginning and end of the study, after the eligible individuals have been selected and grouped, the researcher and the assistant coach in charge measure the participants' throwing distance and the individuals' muscular strength using a hand grip device, and the results before and after are compared and evaluated based on existing standards.

3

Description
On some biochemical parameters (serum levels of lactate dehydrogenase, creatine kinase, serum zinc, growth hormone, IGF1 and testosterone)
Timepoint
Beginning and end of the study
Method of measurement
At the beginning and end of the study, a 5cc blood sample will be taken the morning after the training session, following a 10 to 12 hour fast, to determine serum levels of some biochemical indicators, including serum levels of creatine kinase, growth hormone, IGF1, lactate dehydrogenase, serum zinc, testosterone, fasting blood sugar, and lipid profile.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 12 athletes from Tabriz city, whose anthropometric measurements, sports performance, blood sampling and questionnaire completion will be taken at the beginning of the study. Then, these individuals will receive 30 mg zinc gluconate supplement, 1 tablet daily for 8 weeks, and again at the end of the study, measurements related to anthropometry, sports performance, blood sampling and questionnaire completion will be taken.
Category
Treatment - Drugs

2

Description
Control group: 12 Boccia athletes from Tabriz city, who will have anthropometric measurements, sports performance, blood sampling, and questionnaire completion at the beginning of the study. Then, these individuals will receive 1 tablet of maltodextrin placebo with the same dose, volume, shape, size, taste, and smell daily for 8 weeks, and again at the end of the study, measurements related to anthropometry, sports performance, blood sampling, and questionnaire completion will be taken.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Welfare Organization
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
Tabriz 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

Name of organization / entity
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Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there are not extra data more than results presented in our articles

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available