

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effect of acute oral ketone supplementation on the response of some appetite-related peptides to one-bout of sprint intermittent exercise in overweight men

#### Protocol summary

##### Study aim

Investigating the effect of acute oral ketone supplementation on the response of some appetite-related peptides to one-bout of sprint intermittent exercise in overweight men

##### Design

This research will be conducted as a randomized, crossover, double-blind clinical trial on two groups, each consisting of 8 participants.

##### Settings and conduct

After recruiting volunteers at the university, they will be asked to provide personal information (age, height, weight, and daily physical activity) and participate in a session where the research objectives and methodology will be explained to them. After completing the consent forms, initial measurements (body composition, maximum aerobic capacity, anaerobic power, and maximal fat oxidation) will take place. Then, 16 participants will be randomly selected and assigned to two homogeneous groups (group one: placebo plus exercise, group two: ketone salt supplementation plus exercise). blood samples will be collected before and after consumption.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Being a male Being 18 to 35 years old Having BMI between 25 to 30 exclusion criteria: Having a history of any kind of injury Being a regular smoker Diagnosed with chronic diseases Followed a ketogenic diet in the past six months

##### Intervention groups

Intervention group: The intervention involves consuming a single serving of ketone salt (KETO CaNa), a dietary supplement produced by KETO SPORTS in the United States. Each serving weighs 19 grams and contains 11.7 grams of beta-hydroxybutyrate, 1.1 grams of calcium, 1.3 grams of sodium, and 55 calories. It will be provided to the participants as a solution dissolved in 300

milliliters of water. Control group: The control group will consume an isocaloric and isovolume placebo consisting of oral glucose and flavoring, dissolved in 300 milliliters of water.

##### Main outcome variables

The appetite rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230721058875N1**

Registration date: **2023-09-14, 1402/06/23**

Registration timing: **prospective**

Last update: **2023-09-14, 1402/06/23**

Update count: **0**

##### Registration date

2023-09-14, 1402/06/23

##### Registrant information

##### Name

Alireza Esmailiyan

##### Name of organization / entity

Shahid Beheshti University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6557 6308

##### Email address

a.esmailiyan.sbu.ac.ir@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-24, 1402/07/02

**Expected recruitment end date**

2023-10-04, 1402/07/12

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of acute oral ketone supplementation on the response of some appetite-related peptides to one-bout of sprint intermittent exercise in overweight men

**Public title**

The effect of acute oral ketone supplementation on the response of some appetite-related peptides to one-bout of sprint intermittent exercise in overweight men

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being a male Being 18 to 35 years old Having BMI between 25 to 30

**Exclusion criteria:**

Having a history of any kind of injury Being a regular smoker Diagnosed with chronic diseases Followed a ketogenic diet in the past six months

**Age**

From **18 years** old to **35 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **16**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After initial evaluations, participants will be randomly allocated into two homogeneous groups (Groups A and B) based on body mass index, maximum oxygen consumption, and aerobic power (Wingate). This randomization process will be carried out using IBM SPSS statistical software through simple randomization. The allocation will be done individually by a third party, ensuring that each participant is assigned to either Group A or Group B to prevent bias in group assignments.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Using edible flavorings, food supplement beverages, or glucose placebo beverages, identical in terms of volume, calories, taste, and smell, will be prepared by a third party. These solutions will be dissolved in three hundred

milliliters of water and provided to the participants in identical opaque cups. Both the participants and the researchers responsible for data collection and evaluation will not know the order of consumption of the food supplement beverage or glucose placebo beverage.

**Placebo**

Used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Shahid Beheshti University

**Street address**

Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2023-05-29, 1402/03/08

**Ethics committee reference number**

IR.SBU.REC.1402.082

**Health conditions studied****1****Description of health condition studied**

Overweight

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

**Primary outcomes****1****Description**

The appetite rate

**Timepoint**

The appetite rate will be evaluated just before consuming the beverage and once every thirty minutes for two hours.

**Method of measurement**

The appetite rate will be measured using a visual analog scale.

## Secondary outcomes

### 1

#### **Description**

The calorie intake

#### **Timepoint**

The calorie intake in a meal going to be evaluated two hours after consuming the beverage.

#### **Method of measurement**

The number of calories consumed will be calculated by weighing the amount of food in the container before and after consumption using a digital scale.

### 2

#### **Description**

The blood ghrelin level

#### **Timepoint**

The blood ghrelin level will be measured right before consuming the drink, one hour, and two hours after consuming it.

#### **Method of measurement**

The blood ghrelin level will be checked using Enzyme-Linked Immunosorbent Assay (ELISA) kits.

### 3

#### **Description**

The blood beta-hydroxybutyrate level

#### **Timepoint**

The blood beta-hydroxybutyrate level will be measured right before consuming the drink, one hour, and two hours after consuming it.

#### **Method of measurement**

The blood beta-hydroxybutyrate levels will be checked using biochemical kits.

### 4

#### **Description**

The blood insulin level

#### **Timepoint**

The blood insulin level will be measured right before consuming the drink, one hour, and two hours after consuming it.

#### **Method of measurement**

The blood insulin level will be checked using Enzyme-Linked Immunosorbent Assay (ELISA) kits.

### 5

#### **Description**

The blood leptin level

#### **Timepoint**

The blood leptin level will be measured right before consuming the drink, one hour, and two hours after consuming it.

#### **Method of measurement**

The blood leptin level will be checked using Enzyme-Linked Immunosorbent Assay (ELISA) kits.

### 6

#### **Description**

The blood glucose level

#### **Timepoint**

The blood glucose level will be measured right before consuming the drink, one hour, and two hours after consuming it.

#### **Method of measurement**

The blood glucose level will be checked using biochemical kits.

### 7

#### **Description**

The blood lactate level

#### **Timepoint**

The blood lactate level will be measured right before consuming the drink, one hour, and two hours after consuming it.

#### **Method of measurement**

The blood lactate level will be checked using biochemical kits.

## Intervention groups

### 1

#### **Description**

Intervention group: The intervention involves consuming a single serving of ketone salt (KETO CaNa), a dietary supplement produced by KETO SPORTS in the United States. Each serving weighs 19 grams and contains 11.7 grams of beta-hydroxybutyrate, 1.1 grams of calcium, 1.3 grams of sodium, and 55 calories. It will be provided to the participants as a solution dissolved in 300 milliliters of water.

#### **Category**

N/A

### 2

#### **Description**

Control group: The control group will consume an isocaloric and isovolume placebo consisting of oral glucose and flavoring, dissolved in 300 milliliters of water.

#### **Category**

Placebo

## Recruitment centers

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Beheshti University

##### **Full name of responsible person**

Alireza Esmailiyan

##### **Street address**

Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran, Iran

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University  
**Full name of responsible person**  
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**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
self-fund  
**Proportion provided by this source**  
100  
**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Persons

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University  
**Full name of responsible person**  
Alireza Esmailiyan  
**Position**  
Master's student  
**Latest degree**

Bachelor  
**Other areas of specialty/work**  
Sport Medicine  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

Yes - There is a plan to make this available

### **Informed Consent Form**

No - There is not a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

Not applicable

### **Data Dictionary**

Yes - There is a plan to make this available

### **Title and more details about the data/document**

All data obtained from this study will be statistically analyzed, and relevant conclusions will be drawn to form a research article. After undergoing peer review, the article will be published in a scientific journal. The personal information and details of the participants will

not be disclosed in accordance with ethical principles.

### **When the data will become available and for how long**

after the results are published in a scientific article, the study data will be accessible. This means that the collected data, along with the corresponding results and conclusions, will be made available for reference and utilization by other researchers and interested individuals.

### **To whom data/document is available**

Those who have permission to access data and documents include participants in the study, members of the research team, interested persons, and relevant officials. Of course, access to data must be done in compliance with ethical principles, privacy, and relevant laws.

### **Under which criteria data/document could be used**

Data and documentation will be used to provide scientific information and evidence for further research, and statistical analysis, confirm or reject hypotheses, develop new theories, evaluate and analyze previous results, and support related decisions in various fields.

### **From where data/document is obtainable**

The data will be readily accessible by simply visiting the website of the scientific journal publishing the research article.

### **What processes are involved for a request to access data/document**

The data will be readily accessible by simply visiting the website of the scientific journal publishing the research article.

### **Comments**