Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
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+98 21 6557 6308
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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 dieses 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
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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?
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
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Alireza Esmailiyan
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Sport Medicine
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Person responsible for updating data

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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