Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of Descurainia sophia (L.) Webb ex prantl on hydration, thirst status, and fatigue in recreational athletes

Protocol summary

Study aim

Determining the effect of Descurainia sophia on the state of hydration, thirst and fatigue in non-professional athletes

Design

A controlled, parallel-group, randomized clinical trial on 32 non-professional cyclists. Randomization was done by random block method.

Settings and conduct

In order to collect the samples, the non-professional cycling teams of Urmia will be referred and informed.Sampling will be done by available sampling method.Candidates will be randomly divided into two groups. The volunteers of both groups are asked to drink about 400-600 ml (500 ml on average) equivalent to 14-22 oz of water the night before the trial before going to sleep . They are also asked to drink 250 ml of water immediately after waking up on the day of the experiment. Volunteers of both groups should drink 250 ml of sports drink (syrup containing 6.25 grams of brown sugar per 100 ml) (placebo) or syrup containing 2 grams of Descurainia sophia powder and 6.25 grams of brown sugar 30 minutes before the start of the experiment.

Participants/Inclusion and exclusion criteria

Non-professional cyclists aged 18 to 40 volunteered to participate in the study with a body mass index in the normal range (24.9 to 18.5).

Intervention groups

Volunteers of both groups should drink 250 ml of sports drink (syrup containing 6.25 grams of brown sugar per 100 ml) (placebo) or syrup containing 2 grams of Descurainia sophia powder and 6.25 grams of brown sugar 30 minutes before the start of the experiment. Drink 100 ml at a temperature of 15 degrees Celsius and run on a treadmill in a controlled environment for 45 minutes with 80% of the maximum oxygen consumption.

Main outcome variables

In case of clinical and practical confirmation of the effect of Descurainia sophia in improving hydration indicators and quenching thirst in athletes, this plant can be recommended for athletes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201010048982N3**
Registration date: **2024-11-04, 1403/08/14**
Registration timing: **prospective**

Last update: **2024-11-04, 1403/08/14**
Update count: **0**

Registration date

2024-11-04, 1403/08/14

Registrant information

Name

Farkhondeh Alami

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 45 3333 7906

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

Expected recruitment end date

2025-03-18, 1403/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison the effect of Descurainia sophia (L.) Webb ex prantl on hydration, thirst status, and fatigue in recreational athletes

Public title
Investigating the effect of Descurainia sophia (L.) Webb ex prantl on hydration, thirst status, and fatigue in recreational athletes

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
- Non-professional cyclists 18-40 years old who volunteered to participate in the study with BMI in the normal range (24/9-18/9)

Exclusion criteria:
- Diagnosis of any systemic disease that may be aggravated by participating in the study - People with abnormal liver function or abnormal kidney function - Women who are pregnant or breastfeeding, or intending to become pregnant - People with blood pressure above 140/90 mmHg or high blood pressure with the use of a diuretic - People with a history of asthma or allergic disease - People with a history of alcohol addiction, drug addiction, or mental illness - People with chronic cardiovascular, metabolic, respiratory diseases, recent muscle and skeletal injuries, previous history of heat stroke during the last 3 years - People with a history of hay fever allergy based on self-report

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible samples will be randomly divided into intervention and control groups. The intervention groups will be given codes A, B, C and the control group will receive code D. The study blocking is as follows: All block modes of these 4 groups are 24 numbers: ABCD, ABDC, ACDB, ACBD, ADBC, ADCB, BACD, BADC, BCAD, BCDA, BDAC, BDCA, CABD, CADB, CBAD, CBDA , CDAB, CDBA, DABC, DASB, DBCA, DBAC, DCAB, DCBA. These blocks will be placed in sealed envelopes inside a container. Then they will be drawn one by one, the first block to be removed will be selected as the first block. In fact, this will be repeated 28 times to complete the sample size. In this way, people enter the study and thus will be divided into groups.

Blinding (investigator's opinion)
Not 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 urmia university of medical sciences

Street address
Urmia University of Medical Sciences. Resalat Blvd. Emergency room

City
Urmia

Province
West Azarbaijan

Postal code
5614687911

Approval date
2024-11-21, 1403/09/01

Ethics committee reference number
IR.UMSU.REC.1403.200

Health conditions studied

1

Description of health condition studied
Investigating the state of hydration, thirst and fatigue in non-professional athletes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Thirst evaluation questionnaire will be done at the beginning of the trial and after the end of the study period using the thirst evaluation questionnaire and visual analog scale (VAS) 10 cm self-rating, where zero means no desire to consume liquids and ten means It means extreme thirst.The volunteers' fatigue assessment questionnaire will be completed by the volunteers at the beginning of the trial (minute zero) and after the study period.The volunteers' urine samples will be taken at 0 (before the start of running), 45, 70, 95 and 120 minutes during the trial and will be collected in urine sample containers for analysis. The color and specific density of urine will be measured visually and using a digital refractometer at the mentioned time

intervals.

Timepoint

The test will be conducted in controlled conditions (temperature 35°C, relative humidity 30% and cooler temperature 26°C) on a treadmill for 45 minutes.Urine samples of volunteers will be taken at 0 (before the start of running), 45, 70, 95 and 120 minutes during the trial and will be collected in urine sample containers for analysis.Volunteers' blood samples will be taken at 0, 45, and 120 minutes during the trial, and blood analyzes will be performed including measurement of plasma volume and hematocrit.The heart rate of the volunteers will be measured at 0, 45, 70, 95 and 120 minutes during the trial period. Thirst evaluation questionnaire at the beginning of the experiment and after the end of the study period will be completed by the volunteers using the thirst evaluation questionnaire and the fatigue evaluation questionnaire of the volunteers at the beginning of the experiment (zero minute) and after the study.

Method of measurement

Fatigue and thirst questionnaire, refractometer and blood tests to check the specific density of urine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Non-professional cyclists drank a syrup containing 2 grams of Descurainia sophia powder and 6.25 grams of brown sugar per 100 ml at a temperature of 15 degrees Celsius 30 minutes before the start of the trial and in a controlled environment for 45 minutes with 80% Maximum oxygen consumption run on a treadmill.

Category

Lifestyle

2

Description

Control group: The non-professional cyclist drank 250 ml of sports drink (syrup containing 6.25 g of brown sugar per 100 ml) (placebo) 30 minutes before the start of the test and in controlled environmental conditions for 45 minutes with 80% oxygen. Maximum consumption of running on a treadmill.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia university of medical sciences

Full name of responsible person

Savana Dangian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person
Sevana Dangian
Position
Consultant
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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
IPD collected for the primary outcome measure only, etc).
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
After the request of the researchers, and after the publication of the article extracted from this work, the documents will be provided to them
From where data/document is obtainable
Email Dr. Savana Dangyan. Contact number: 09386658388
What processes are involved for a request to access data/document
After the request of the researchers, the documents will be provided to them
Comments
We have no special comment