

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of carbohydrate mouth rinsing on functional capacity in overweight women

Protocol summary

Study aim

The aim of the study is the evaluation of the effect of carbohydrate mouth rinsing on functional capacity including time to exhaustion and rating of perceived exertion during exercise in overweight women.

Design

Two arms parallel group randomised trial with blinded participants and outcome assessor

Settings and conduct

The study is conducting in Emam Khomeini Hospital. All of the subjects participate in two sessions of Bruce test: the first test will be done on all of the participants without mouth rinsing (baseline test). The second test will be done with mouth rinsing with a carbohydrate solution (intervention group) or simple water (control group). Assessor and participants will be blind to the content of the solutions.

Participants/Inclusion and exclusion criteria

Female sex; Without pregnancy or regular physical activity or cigarette smoking; Without any diseases that affect the heart rate, diet or physical activity; Without significant weight reduction over the past 6 months.

Intervention groups

The study has two groups: 1) Carbohydrate solution mouth rinsing 2) Simple water mouth rinsing. both of groups have an exercise test with Bruce protocol on the treadmill till maximal exhaustion.

Main outcome variables

Functional capacity; Time to exhaustion; Rating of perceived exertion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111025007903N10**

Registration date: **2019-02-13, 1397/11/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-13, 1397/11/24**

Update count: **0**

Registration date

2019-02-13, 1397/11/24

Registrant information

Name

Zahra Alizadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of carbohydrate mouth rinsing on functional capacity in overweight women

Public title

Carbohydrate mouth rinsing and functional capacity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female sex Without pregnancy or regular physical activity or cigarette smoking Without any diseases that affect the heart rate, diet or physical activity Without significant weight reduction over the past 6 months

Exclusion criteria:

Refuse participation in the trial

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

We use simple randomization by a table of random numbers. Allocation concealment is done by the bottles that the content of them is not visible. The assessor and the participants will be blind to the content of the bottles.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, investigator and data analyser are blind. A co-worker who does not participate in the other trial sections delivers the carbohydrate solution or simple water to the participants according to a randomization table.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd

City

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Province

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Postal code

1417653761

Approval date

2018-05-20, 1397/02/30

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.267

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Functional capacity

Timepoint

Baseline and 72 hours later

Method of measurement

Running time on treadmill and Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the group will rinse the 6% carbohydrate solution every 5 minutes till to exhaustion on the treadmill. The time to exhaustion will be compared with baseline.

Category

Prevention

2

Description

Control group: the group will rinse the simple water solution every 5 minutes till to exhaustion on the treadmill. The time to exhaustion will be compared with baseline.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini hospital

Full name of responsible person

Faezeh Maleklou
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Emam Khomeini hospital complex., Dr. Gharib St.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
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
Tehran 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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Person responsible for updating data

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Web page address**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

Primary outcomes and others according to researchers request

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Please contact with this e-mail: z_alizadeh@tums.ac.ir

Under which criteria data/document could be used

Please contact with this e-mail: z_alizadeh@tums.ac.ir

From where data/document is obtainable

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

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Comments