

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of beetroot juice supplementation on functional capacity in overweight women

#### Protocol summary

##### Study aim

The effect of beetroot juice (nitrate supplement) on functional capacity of overweight women.

##### Design

Clinical trial with control group, double blind, randomized by random number table.

##### Settings and conduct

Aerobic test with basic RAMP protocol and strength test of chest press and leg press with 70% of maximum strength is taken. At the end, RPE is recorded with using a visual questionnaire. At the next visit, patients drink juice (one group of colored water as a placebo and the other group of beetroot juice) 2.5 hour before the test and then the RAMP test and the strength test of the chest press and foot press are taken again.

##### Participants/Inclusion and exclusion criteria

1-Women with BMI 25 to 29.9 kg per m<sup>2</sup>; 2- Age range 45-20 years old; 3- Physical activity less than 90 minutes with moderate intensity per week in at least the last three months; 4- No history of disease (uncontrolled diabetes, severe cardiovascular disease, musculoskeletal limitations and exercise-limiting neurological disorder, uncontrolled hypertension, chronic obstructive pulmonary disease).

##### Intervention groups

In the case group, beetroot juice and in the control group, water is dyed with food colors is given to samples.

##### Main outcome variables

Time to get fatigue on the treadmill; Number of repetitions of chest press until fatigue; Number of repetitions of leg press until fatigue; Understanding the difficulty of working while running on a treadmill.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201203049583N1**

Registration date: **2020-12-15, 1399/09/25**

Registration timing: **prospective**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

##### Registration date

2020-12-15, 1399/09/25

##### Registrant information

###### Name

Mina Najmabadi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8822 3257

###### Email address

najmabadi.mina@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2021-12-22, 1400/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of beetroot juice supplementation on functional capacity in overweight women

##### Public title

The effect of beetroot juice supplementation on functional capacity in overweight women

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women with BMI 25 to 29.9 kg/m<sup>2</sup> Age range: 20-45 years old Physical activity less than 90 minutes with moderate intensity per week in at least the last three months No history of disease (uncontrolled diabetes, severe cardiovascular disease, musculoskeletal limitations and exercise-limiting neurological disorder, uncontrolled hypertension, chronic obstructive pulmonary disease)

### Exclusion criteria:

Creating restrictive musculoskeletal problems that prevent continued physical activity The presence of signs and symptoms that put a person at high risk for heart disease Reluctance to continue cooperation

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Women with inclusion criteria, after entering, are numbered in order and then identified by numbers. At the first visit, each sample is entered into one of the two case and control groups by a table of random numbers Even numbers are in one group and odd numbers are in another Numbering and division into two groups without coordination with the patient

## Blinding (investigator's opinion)

Double blinded

## Blinding description

One group is given of colored water (with authorized food colors) as a placebo and the other group is given beetroot juice, and this process is done by a person other than the researcher who is responsible for collecting data.

## 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 science

#### Street address

Building No. 1 of the Faculty of Medicine, First Floor, Office of the Vice Chancellor for Research, North Door of the University, Poursina St., Ghods St., Enghelab St.

#### City

Tehran

#### Province

Tehran

#### Postal code

1417613151

#### Approval date

2020-04-15, 1399/01/27

#### Ethics committee reference number

IR.TUMS.IKHC.REC.1399.076

## Health conditions studied

## 1

### Description of health condition studied

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

## 1

### Description

Functional capacity ( Time to exhaustion in activity)

### Timepoint

Initial referral and referral on the 7th and 14th day

### Method of measurement

Borg scale

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: In the initial referral, how to perform and how to test is explained. In the second visit, the fatigue time test is performed using the Ramp protocol. 1RM test was taken for chest and leg presses. People are taught not to exercise 12 hours before the aerobic function test and to have breakfast two hours before the test, to avoid diuretics and alcohol at least 12 hours before the test, to use substances such as caffeine and chocolate. Limit 24 hours before the test. Tests are taken between 8 and 10 am. At the end of the test, the difficulty of understanding the work is recorded by the previously trained Borg visual index. The strength test

was then performed at 70% 1RM in two sets with as many repetitions as they could perform, two minutes apart. At the end of each test, the perception of difficulty was recorded by the Borg visual index. 1RM is taken from patients by observing the above points

**Category**

Treatment - Other

**2****Description**

Control group: The initial referral explains how to do and how to test. In the second visit, the fatigue time test is performed using the Ramp protocol. 1RM test was taken for chest and leg presses. People are taught not to exercise 12 hours before the aerobic function test and to have breakfast two hours before the test, to avoid diuretics and alcohol at least 12 hours before the test, to use substances such as caffeine and chocolate. Limit 24 hours before the test. Tests are taken between 8 and 10 am. At the end of the test, the difficulty of understanding the work is recorded by the previously trained Borg visual index. The strength test was then performed at 70% 1RM in two sets with as many repetitions as they could perform, two minutes apart. At the end of each test, the difficulty of understanding the work was recorded by the Borg visual index. RAMP test, chest press and leg press with 70% 1RM will be taken from patients by observing the above points.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Mina Najmabadi

**Street address**

The end of Keshavarz Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6693 8081

**Email**

imamhospital@tums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Deputy of research and technology

**Street address**

corner of Quds Street, University Central Organization, 6th floor, Keshavarz Blvd

**City**

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**Province**

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1417653761

**Phone**

+98 21 8163 3698

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vcr@tums.ac.ir

**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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mina Najmabadi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Sport Medicine

**Street address**

Department of Sports Medicine, Imam Khomeini hospital, Dr Gharib Ave., End of Keshavarz Blvd.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mina Najmabadi

**Position**

Resident

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Medical doctor

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## Person responsible for updating data

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## Sharing plan

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

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

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