

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Investigating the effect of orange peel extract on the performance and improving the record of Tehrani male swimmers and the time to reach fatigue

#### Protocol summary

##### Study aim

To find out whether orange peel extract has an effect on the performance and improvement of swimmers' records

##### Design

Three groups are used, a placebo group, a single-dose group, and a two-dose group are used in parallel.

##### Settings and conduct

The pre-test and post-test are held in an indoor pool with a temperature of 25 degrees Celsius, 50 meters long and 18 meters wide, and the pooling is done in such a way that one person, who is neither a researcher nor a supervisor or analyst, divides the participants into three groups and the drugs or a placebo is given.

##### Participants/Inclusion and exclusion criteria

Must be Tehrani expert male swimmers between 11 and 18 years old

##### Intervention groups

The intervention is in the form of capsules, which includes a placebo, one dose and two doses, in the placebo, flour is used, and the capsules contain 80% orange peel extract and 20% food additives are allowed.

##### Main outcome variables

Does the extract of orange peel delay the performance and improvement of the record and the time to reach fatigue of Tehrani male swimmers, and the aerobic and anaerobic capacity of the swimmers is evaluated.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221226056935N1**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

##### Registration date

2023-06-26, 1402/04/05

##### Registrant information

###### Name

Seyyed ali Zahedi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7750 1864

###### Email address

s.alizahedi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-28, 1402/04/07

##### Expected recruitment end date

2023-07-19, 1402/04/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of orange peel extract on the performance and improving the record of Tehrani male swimmers and the time to reach fatigue

##### Public title

The effect of orange peel extract on the performance and record improvement of Tehrani male swimmers and the time to reach fatigue

##### Purpose

Basic science

## Inclusion/Exclusion criteria

### Inclusion criteria:

Only expert swimmers, Tehrani boys, 11 to 18 years old, Nofalah pool

### Exclusion criteria:

## Age

From **11 years** old to **18 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **24**

## Randomization (investigator's opinion)

Randomized

## Randomization description

24 expert male swimmers from Tehran will be randomized into three groups of 8 people and will be used in the form of code in the rest of the research (group one placebo, group two one dose of drug and group three two rounds of drug) and because of this randomization, each person There is an equal chance to be placed in each of the groups that the researchers and participants in the study are not able to predict the type of intervention received, and the first step is to create a random sequence and the second step is to hide the sequence, which increases the reliability of the research. will be.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

It is the case that a third person other than the researcher and the supervisor and the participants in the research is present to eliminate the psychological effect of the drug or orange peel extract supplement so that the results of the work show the real effect of the drug to the researcher.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Assistant Azad University of Tehran, Sohank

Center

## Street address

Province complex Islamic Azad University, Central Tehran branch The big end of the army road, Tehran, Iran

## City

tehran

## Province

Tehran

## Postal code

1955847881

## Approval date

2023-06-21, 1402/03/31

## Ethics committee reference number

IR.IAU.CTB.REC.1402.010

## Health conditions studied

### 1

#### Description of health condition studied

Effect of orange peel extract on aerobic and anaerobic performance

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Orange peel extract and sympathetic imitation

#### Timepoint

21. After eating the test capsule, the post-test will be taken

#### Method of measurement

Chronometer and recording

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:A medicinal dose (one capsule) is given.

#### Category

Diagnosis

### 2

#### Description

Intervention group: Two doses of medicine (two capsules) are given.

#### Category

Diagnosis

**3**

**Description**

Control group: It is given from empty capsules containing flour.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Nofalah pool in Tehran

**Full name of responsible person**

Seyyed Ali Zahedi

**Street address**

Shahid Nofalah pool, Next to the wrestling hall  
Workash St Muftah St., Tehran, Iran

**City**

tehran

**Province**

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**Postal code**

1573613131

**Phone**

+98 21 8883 5350

**Email**

s.alizahedi@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mohammad Ali Azarbayjani

**Street address**

Province complex Azad University of Tehran, Sohank  
Center Shahid Sohani St., The big end of the army  
road, Tehran, Iran

**City**

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**Province**

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**Phone**

+98 21 7368 1103

**Email**

ali.azarbayjani@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Clothing retail

**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**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

seyyed ali zahedi

**Position**

A student studying

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiology

**Street address**

Unit 4, No. 1, Blossom dead end Shahid Hodayun  
Natghi St., Shemiran Gate, Tehran, Iran

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**Province**

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**Postal code**

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**Phone**

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**Email**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

seyyed ali zahedi

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**Person responsible for updating data**

**Contact**

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**Email**

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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**

According to the supervisor's decision

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

According to the supervisor's decision

**To whom data/document is available**

According to the supervisor's decision

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

According to the supervisor's decision

**From where data/document is obtainable**

According to the supervisor's decision

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

According to the supervisor's decision

**Comments**