

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison of some immune response in serum and saliva at healthy men after one bout of exhaustive aerobic exercise

#### Protocol summary

##### Study aim

Comparison of some immune response in serum and saliva at healthy men after one bout of exhaustive aerobic exercise

##### Design

This study is a non-randomized clinical trial and it will be a single group.

##### Settings and conduct

This clinical trial study will be conducted in physical education hall of Tabriz University of Medical Sciences. Intervention group will be measured during one exercise session on criteria such as cortisol in saliva and urine sample.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included: age between 19-21, having no infectious and inflammatory disease and being male, and exclusion criteria included being female and having the disease.

##### Intervention groups

The intervention group consists of individuals who will participate in an exhausting exercise session and then measure what will be needed.

##### Main outcome variables

Cortisol

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200119046192N1**

Registration date: **2020-03-01, 1398/12/11**

Registration timing: **prospective**

Last update: **2020-03-01, 1398/12/11**

Update count: **0**

##### Registration date

2020-03-01, 1398/12/11

#### Registrant information

##### Name

iran akhtari shojaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3336 4901

##### Email address

akhtary20@yahoo.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2020-03-05, 1398/12/15

#### Expected recruitment end date

2020-03-20, 1399/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of some immune response in serum and saliva at healthy men after one bout of exhaustive aerobic exercise

#### Public title

Comparison of some immune response in serum and saliva

#### Purpose

Diagnostic

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

21>age>19 Male No inflammatory disease

##### Exclusion criteria:

Female Presence of infection disease

#### Age

From **19 years** old to **21 years** old

**Gender**  
Male

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**  
Ethics committee of tabriz university of medical sciences

**Street address**  
No.65., Azadi aveu., amirkabir street

**City**  
tabriz

**Province**  
East Azarbaijan

**Postal code**  
5173814834

**Approval date**  
2020-01-04, 1398/10/14

**Ethics committee reference number**  
lr.tbzmed.rec.1398.1094

## Health conditions studied

### 1

**Description of health condition studied**  
Cortisol

**ICD-10 code**  
Y93.A3

**ICD-10 code description**  
Activity, aerobic and step exercise

## Primary outcomes

### 1

#### Description

Cortisol

#### Timepoint

قبل از انجام مداخله و بلافاصله بعد از انجام مداخله

#### Method of measurement

Eliza method

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The group will attend a post-exercise exercise session after the study; cortisol levels will be measured before and immediately after the intervention through saliva and serum samples. The hormone will be measured with the help of an ELISA device.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
University of Tabriz

**Full name of responsible person**  
Ebrahim Akhtari shojaei

**Street address**  
No. 65, Azadi Street., AmirKabir

**City**  
Tabriz

**Province**  
East Azarbaijan

**Postal code**  
5173814834

**Phone**  
+98 41 3441 5683

**Email**  
Akhtary20@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tabriz University of Medical Sciences

**Full name of responsible person**  
Ebrahim Akhtarishojaei

**Street address**  
No.65, Azadi Street., Amirkabir

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**Email**

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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**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ebrahim Akhtari Shojaei

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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## Person responsible for scientific inquiries

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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