

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jun 2026

### Investigating the effect of drinking green tea on the total antioxidant capacity (TAC) of saliva in young smokers and non smokers

#### Protocol summary

##### Study aim

Investigating the effect of drinking green tea on the total antioxidant capacity (TAC) of saliva in young smokers and non-smokers

##### Design

A clinical trial with a control group, with parallel groups, double-blind, with an accessible and non-random sampling method, the trial phase does not include divisions and on 40 people.

##### Settings and conduct

All participants were asked to consume a total of two cups of green tea per day for three weeks. Each cup is prepared by brewing 2 grams of green tea (one green tea bag) in 150 ml of hot water (80 degrees Celsius) for 3 minutes. Then, unstimulated saliva samples are collected once at the beginning of the study and once at the end of the intervention, and the TAC of the samples is measured in the laboratory with the FRAP test. Venue: Birjand University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: the age of people should be between 20 and 27 years old and the population studied should be students of Birjand University of Medical Sciences. Exclusion criteria: existence of systemic pulmonary diseases and use of medicine or vitamin supplements in the last 3 months

##### Intervention groups

20 healthy smoking volunteers and 20 healthy non-smoking volunteers are asked to consume two cups of green tea per day for three weeks. Then, unstimulated saliva samples are collected once at the beginning of the study and once at the end of the intervention, and the TAC value of the samples is measured in the laboratory with the FRAP test.

##### Main outcome variables

Total antioxidant capacity (TAC) of saliva

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231230060572N1**

Registration date: **2024-05-14, 1403/02/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-05-14, 1403/02/25**

Update count: **0**

##### Registration date

2024-05-14, 1403/02/25

##### Registrant information

##### Name

Sajjad Shariati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3238 1704

##### Email address

s.shariati10@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-08, 1403/01/20

##### Expected recruitment end date

2024-07-10, 1403/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of drinking green tea on the total antioxidant capacity (TAC) of saliva in young smokers and non smokers

#### Public title

Investigating the effect of drinking green tea on the total antioxidant capacity (TAC) of saliva in young smokers and non smokers

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The age of people should be between 20 and 27 years  
The study population is students of Birjand University of Medical Sciences

##### Exclusion criteria:

Presence of systemic pulmonary diseases  
Use of medicine or vitamin supplements in the last 3 months

#### Age

From **20 years** old to **27 years** old

#### Gender

Male

#### Phase

N/A

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The intervention is designed in such a way that the people under study or the participants and the people who are responsible for evaluating and analyzing the data do not know about the allocation of the intervention groups and are kept blind.

#### Placebo

Not used

#### Assignment

Other

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

##### Street address

Birjand University of Medical Sciences, Moalem Street

#### City

Birjand

#### Province

South Khorasan

#### Postal code

9717853-76

#### Approval date

2023-10-23, 1402/08/01

#### Ethics committee reference number

IR.BUMS.REC.1402.327

## Health conditions studied

### 1

#### Description of health condition studied

Total antioxidant capacity of saliva

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Total antioxidant capacity of saliva

#### Timepoint

Measuring the total antioxidant capacity of saliva at the beginning of the study (before the start of the intervention) and three weeks after drinking green tea

#### Method of measurement

Determination of the total antioxidant capacity of saliva in the laboratory by spectrophotometer in terms of micromol/liter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first Intervention group: 20 healthy smoking volunteers were asked to consume a total of two cups of green tea per day for three weeks. Each cup is prepared by brewing 2 grams of green tea (one green tea bag) in 150 ml of hot water (80 degrees Celsius) for 3 minutes. Then, unstimulated saliva samples are collected once at the beginning of the study and once at the end of the intervention, and the TAC value of the samples is measured in the laboratory with the FRAP test.

#### Category

Prevention

### 2

#### Description

The second intervention group: 20 healthy non-smoking volunteers were asked to consume a total of two cups of green tea per day for three weeks. Each cup is prepared

by brewing 2 grams of green tea (one green tea bag) in 150 ml of hot water (80 degrees Celsius) for 3 minutes. Then, unstimulated saliva samples are collected once at the beginning of the study and once at the end of the intervention, and the TAC value of the samples is measured in the laboratory with the FRAP test.

**Category**

Prevention

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

Birjand University of Medical Sciences

**Full name of responsible person**

Sajjad Shariati

**Street address**

Birjand University of Medical Sciences, Moalem Blvd

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

s.shariati10@gmail.com

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

Birjand University of Medical Sciences

**Full name of responsible person**

Mona Chahkandi

**Street address**

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**Email**

Dentresearch@bums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

Sajjad Shariati

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

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s.shariati10@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Sajjad Shariati

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Sajjad Shariati

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

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s.shariati10@gmail.com

**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