

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The effectiveness of Vitamin C on the Level of Salivary Total Antioxidant Capacity(TAC) in bruxism patients

#### Protocol summary

##### Study aim

Evaluation the effectiveness of Vitamin C on the level of Total Antioxidant Capacity (TAC) in bruxism patients

##### Design

This clinical trial with a sample size of 30 people was a three-phase, double-blind study with parallel groups. Block randomization was performed in six-piece block individually by a sealed envelope. The random sequence was determined by draw.

##### Settings and conduct

The study population was patients with bruxism of Dentistry Faculty of Tehran University of Medical Sciences in international campus branch. After the examination, completing the questionnaire, and evaluating the patients' pain severity by numerical rating scale, 1 mm non- excitatory and excitatory saliva was collected from the patients. Then, 250 mg vitamin C was prescribed for the intervention group and one daily was given to the placebo control group. Eventually, after a month, their pain was measured and their excitatory and non- excitatory saliva was collected. In order to blinding, the medications were put into boxes of one color and one form, and the difference was the code on which they were inserted; the list was kept by clinical caregiver until decoded. The patient, researcher, outcome evaluator, and data analyzer are kept compared to the blinded study groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: symptoms of grinding teeth on each other, discomfort and fatigue, increase in the size of masticatory muscles. toothpicking, recurrent migraines, broken dental fillings or splint, ulceration of denture underlying mucosa and sensitivity to percussion.  
Exclusion criteria: consumption of alcohol and cigarettes and specific medications, systemic problems (diseases of kidney and liver, thyroid and diabetes) and cancer

##### Intervention groups

This study was conducted on a control group of 15 patients with placebo and the intervention group of 15

patients with vitamin C.

##### Main outcome variables

Total Antioxidant Capacity of stimulated and unstimulated saliva of patient

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160903029651N2**

Registration date: **2018-03-04, 1396/12/13**

Registration timing: **retrospective**

Last update: **2018-03-04, 1396/12/13**

Update count: **0**

##### Registration date

2018-03-04, 1396/12/13

##### Registrant information

##### Name

hodays yeganehfard

##### Name of organization / entity

Tehran University of Medical Sciences Faculty of Dentistry international campus

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8835 6837

##### Email address

yhodais@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Center School of Tehran Dentistry Faculty

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2017-10-23, 1396/08/01  
**Actual recruitment start date**  
2017-10-23, 1396/08/01  
**Actual recruitment end date**  
2017-11-22, 1396/09/01  
**Trial completion date**  
empty

**Scientific title**  
The effectiveness of Vitamin C on the Level of Salivary Total Antioxidant Capacity(TAC) in bruxism patients

**Public title**  
The effect of Vitamin C on salivary antioxidant level in patients with bruxism (gnash)

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Our diagnostic criteria for bruxism is considered based on ICSD-R: 1. Symptoms indicating grinding teeth on each other while sleeping 2. Abnormal grinding of teeth 3. Sound of grinding teeth 4. Discomfort of jaw muscle As well as other symptoms stated by Murali: 1. Toothpicking 2. Fatigue of masticatory muscles 3. Recurrent migraines 4. Broken Dental fillings or splint 5. Ulceration of denture underlying mucosa 6. Sensitivity to percussion 7. Increase in the size of the Temporal and Masseter muscles

**Exclusion criteria:**

Those who have the following features are removed from the list: 1. Record of severe trauma and dental surgeries 2. Clinical record of functional disorder (depression and anxiety) and sleep disorders (Apnea and Insomnia) 3. Moderate to high consumption of alcohol and cigarettes 4. Systemic problems (diseases of kidney and liver, thyroid and diabetes) and cancer, pregnant and nursing mothers 5. Taking drugs (Glucocorticoids or Selective Serotonin, edible contraceptives, variety of Antioxidants, Folic acid, Allopurinol such as Zenthine Oxidase Inhibitor) 6. Epilepsy or neurological disorders such as Parkinson's and Alzheimer's 7. Infectious diseases 8. Those who had taken muscle relaxing drugs such as Benzodiazepines 9. Neuromuscular disorders

**Age**  
From **18 years** old to **60 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **30**  
Actual sample size reached: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

Block randomization was done individually through a sealed envelope and the manner of creating random sequences was through draw.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to blinding, the medications were put into boxes of one color and one form, and the difference was the code on which they were inserted; the list was kept hidden by clinical caregiver until decoded.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Dentistry school of Tehran university of medical science

**Street address**

Tehran University of Medical Sciences of Dentistry School, next to Hakim Highway, up to Atomic Energy Organization, end of Kargar Shomali

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955991

**Approval date**

2017-10-21, 1396/07/29

**Ethics committee reference number**

IR.TUMS.DENTISTRY.REC.1396.3757

**Health conditions studied**

**1**

**Description of health condition studied**

bruxism

**ICD-10 code**

F45.8

**ICD-10 code description**

Any other disorders of sensation, function and behaviour, not due to physical disorders, which are not mediated through the autonomic nervous system, which are limited to specific systems or parts of the body, and which are closely associated in time with

**Primary outcomes**

## 1

### Description

Changes the level of Total Antioxidants Capacity (TAC) of stimulated and unstimulated saliva

### Timepoint

Before intervention and one month after

### Method of measurement

Taking 1 ml stimulated and unstimulated saliva samples and measurement of total antioxidant capacity by the ZellBio GmbH (CAT No. ZB-TAC-96A) and (CAT No. ZB-TAC-48A) kits through oxidation-reduction calorimetry

## Secondary outcomes

## 1

### Description

The score of myofascial pain associated with bruxism

### Timepoint

Before intervention and one month after

### Method of measurement

Numeric Scale Rating (NRS)

## Intervention groups

## 1

### Description

Chewing Vitamin C 250 mg/day with the taste of cherry of Osweh Company, chew one of them daily for a month in the morning (30 days).

### Category

Treatment - Drugs

## 2

### Description

Chewing Placebo (Similist to Vitamin C)250 mg/day with the taste of cherry of Osweh Company, chew one of them daily for a month in the morning (30 days).

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry

#### Full name of responsible person

Hodays Yeganehfard

#### Street address

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry, opposite the Shariati Boostan, Mahan St., Khani Abad Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

1894787549

#### Phone

+98 21 5585 1151

#### Email

Yhodais@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry

#### Full name of responsible person

Shamsoulmolouk Najafi

#### Street address

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry, opposite the Shariati Boostan, Mahan St., Khani Abad Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

1894787549

#### Phone

+98 21 5585 1149

#### Email

Najafi\_sh@tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry

#### 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

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry

#### Full name of responsible person

Shamsoulmolouk Najafi

#### Position

mouth disease specialist

#### Latest degree

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry, opposite the Shariati Boostan, Mahan St., Khani Abad Ave.

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**Province**

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**Postal code**

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**Phone**

+98 21 5585 1149

**Fax**

**Email**

Najafi\_sh@tums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry

**Full name of responsible person**

Shamsoulmolouk Najafi

**Position**

mouth disease specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry, opposite the Shariati Boostan, Mahan St., Khani Abad Ave.

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**Phone**

+98 21 5585 1149

**Fax**

**Email**

Najafi\_sh@tums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry

**Full name of responsible person**

Hodays Yeganehfard

**Position**

Dentistry student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

International Campus Branch, Tehran University of Medical Sciences, School of Dentistry, opposite the Shariati Boostan, Mahan St., Khani Abad Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1894787549

**Phone**

+98 21 5585 1149

**Fax**

**Email**

Yhodsais@yahoo.com

**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**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

In the Effect of vitamin C in the level of total antioxidant saliva in patients with bruxism and the consequences resulting from it such as pain relief, only part of the data, such as information on the primary and secondary consequences, can be shared.

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

It will be available one year after publishing

**To whom data/document is available**

Researchers working in the field of dentistry and medicine

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

Any analysis of the data is not allowed and only the documentation is used to obtain its results in order to help other studies.

**From where data/document is obtainable**

Doctor Shamsoulmolouk Najafi, Najafi\_sh@tums.ac.ir  
Hodays Yeganehfard, Yhodsais@yahoo.com

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

At first, an email is sent to the requested people and we waited 3 to 10 days to submit the file

**Comments**