

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 (Similst 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.

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1894787549

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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.

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Phone

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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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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
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Full name of responsible person
Shamsoulmolouk Najafi
Position
mouth disease specialist
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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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
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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