

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation and comparison of the effect of vitamin E on salivary total antioxidant capacity in smokers and non-smokers patients

Protocol summary

Study aim

Effect of Vitamin E on Antioxidant Capacity of Saliva (TAC) of Smokers and Non-Smokers and Comparison with Each Other

Design

Thirty smokers and 30 nonsmokers were randomly divided into two subgroups. Subgroup A and Subgroup B. The study is designed as a cross over. . The samples in this study were randomly selected from two groups and from eligible referral clients. The study is conducted in two parallel subgroups. The study will be double-blind and the study participants and the person providing the drug and the sample collector will be kept blind. The laboratory is aware of the sample type and group. The use of the nonsmoker group has a control group aspect in the study.

Settings and conduct

Subgroup A smokers and non-smokers in the first phase of vitamin E 200 IU daily intake for 3 weeks. Subgroup B smokers and non-smokers in the first phase of placebo take a similar treatment to the original drug for 3 weeks. Thereafter, two subgroup A will take placebo for three weeks and two subgroup B will take vitamin E three weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Smoking at least 5 cigarettes per day or 5 cigarette packs per year Inclusion criteria for non-smokers: Non-smoking during 3 years ago Exclusion criteria: Systemic underlying disease and medication use three weeks before the study

Intervention groups

two groups : Smokers and Non-Smokers using Vit E 200 IU and Placebo

Main outcome variables

Numerical value and mean total salivary antioxidant capacity of the two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110428006322N3**

Registration date: **2021-03-05, 1399/12/15**

Registration timing: **retrospective**

Last update: **2021-03-05, 1399/12/15**

Update count: **0**

Registration date

2021-03-05, 1399/12/15

Registrant information

Name

Mostafa Rezaee

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1635 6681

Email address

rezaim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2016-07-22, 1395/05/01

Trial completion date

2017-02-19, 1395/12/01

Scientific title

Evaluation and comparison of the effect of vitamin E on salivary total antioxidant capacity in smokers and non-smokers patients

Public title

Evaluation of the effect of vitamin E on saliva of smokers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Smokers with the history of 5 or more pack/year of smoking the smoker patients referred to Nader Kazemi Dental Clinic of Shiraz city

Exclusion criteria:

individuals with systemic diseases, dry mouth, history of oral ulcer or any inflammatory oral diseases, alcohol consumption, drug and medication use or supplemental vitamin consumption in the last three months patients with age over 65 years old

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the Restricted randomization method of block randomization. All blocks are the same size as 6, and made by two groups (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software is used to make random sequence (Random allocation software). For allocation concealment, non-transparent sequentially numbered envelopes will be used. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes. Finally, the lids of the letter envelopes will be glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blind study, the participants in the study are kept blind. The laboratory is aware of the sample type and group.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz university of medical sciences

Street address

Shiraz university of medical sciences, Zand blvd

City

Shiraz

Province

Fars

Postal code

71345-1978

Approval date

2016-08-20, 1395/05/30

Ethics committee reference number

IR.SUMS.REC.1395.209

Health conditions studied

1

Description of health condition studied

smoking , Total Antioxidant Capacity , Oral cancer prevention

ICD-10 code

ICD-10 code description

Z58.7

Primary outcomes

1

Description

Total Antioxidant Capacity

Timepoint

Measurement of total salivary antioxidant capacity in the saliva sample of all participants was collected in the first stage before the intervention, 3 weeks after the intervention, then wash out and again 3 weeks later (equivalent to 6 weeks after the start of the intervention). And the measurement is done.

Method of measurement

20 ml of non-stimulated saliva in the sitting position during the period of 9 A.M to 12 A.M collected. The participants spitting in a 50ml. Falcon tube every 60 seconds. According to the status of the participants 5-15 minutes between each time spit break out. Sample stored at 0 to 5 ° C temperature. Samples were centrifuged (Sigma-Germany) at 4000 rpm. , 4 ° C for 10 minutes. Then centrifuged sample carried out by Pasteur Pipette (ISO-Lab, Germany) and placed in 2 ml tubes (ISAN Teb -Iran) in a freezer (Jal tajhiz-Iran) at -70 ° C. Fluorescence recovery after photobleaching (FRAP) technique used to measurement of total antioxidant

capacity of samples. This method is based on the ability of saliva to recover ferric ions to the ferrite in the presence of a substance called TPTZ (2,4,6-Tri(2-pyridyl)-s-triazine), which is used as a reagent, resulting in a blue complex of TPTZ-Fe with a maximum absorption of 593 nm. The amount of salivary oxidation/reduction capacity measured by the concentration of the TPTZ-Fe blue complex by spectrophotometer at 593 nm.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Smokers between the ages of 30 and 70 years old who take a daily dose of 200 IU vitamin E product from Dana Drug Company orally for three weeks.

Category

Diagnosis

2

Description

Control group: Smokers between the ages of 30- 70 years old who take placebo medication made by Dana Pharmaceutical Company and similar to the main drug daily for 3 weeks.

Category

Diagnosis

3

Description

Intervention group: Non smokers between the ages of 30 - 70 years old who take a daily dose of 200 IU vitamin E product from Dana Drug Company orally for three weeks.

Category

Diagnosis

4

Description

Control group: Non Smokers between the ages of 30- 70 years old who take placebo medication made by Dana Pharmaceutical Company and similar to the main drug daily for 3 weeks.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Nader Kazemi dental clinic

Full name of responsible person

Mostafa Rezaee

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Vali Asr Square - Dept. of Square - Faculty of Dentistry, Shiraz University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Mohamadi

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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

Shiraz University of Medical Sciences

Proportion provided by this source

25

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mostafa Rezaee

Position

Associate professor

Latest degree
Specialist
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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)

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

Not applicable

Title and more details about the data/document

In this study, due to the confidentiality of the individual data of the participants, only the executive protocol, data analysis method, and general plan information are shared in the article.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

his only available for people working in academic institutions

Under which criteria data/document could be used

only for research and treatment propose

From where data/document is obtainable

email address

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

Send an email to the planner and contact person to receive the required information. In the absence of the problem, the information required will be less than 2 weeks

Comments