

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Effect of vitamin C on salivary total antioxidant capacity in healthy male smokers

Protocol summary

Registration date: **2018-01-09, 1396/10/19**
Registration timing: **prospective**

Study aim

Effect of vitamin c on salivary total antioxidant capacity

Design

The present study was designed as a randomized clinical trial. 60 smokers who have been referred to oral medicine department of dental school of Rafsanjan University of medical sciences were included in the study. Then, patients were randomly divided into three groups including: control and intervention groups.

Settings and conduct

For the baseline activity, at least 1 mL of each patient's unstimulated saliva collect in the beginning of study. Collected saliva transferre to laboratory and place in specific microtubules immediately. To separate the squamous cells and derbies, samples centrifuge for 15 min. Then, centrifuge samples preserve at -20°C to be assessed later

Participants/Inclusion and exclusion criteria

Healthy male Smokers with the history of 5 or more pack/year of smoking enter to the study. They have no systemic disease, no history of chemotherapy or radiotherapy, do not take any medications continuously during the past 3 months, do not take alcohol and supplements, and do not have nephrolithiasis. They also haveno oral pathology based on clinical examination.

Intervention groups

Group A, receive 1000 mg of vitamin C Effervescent tablets daily and group B receive 500 mg of vitamin C Effervescent tablets per day for three weeks, and the control group does not receive any supplements.

Main outcome variables

Salivary total antioxidant capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171203037717N1**

Last update: **2018-01-09, 1396/10/19**

Update count: **0**

Registration date

2018-01-09, 1396/10/19

Registrant information

Name

nazanin kamyab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0031

Email address

nazanin.kamyab@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-16, 1396/10/26

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin C on salivary total antioxidant capacity in healthy male smokers

Public title

Effect of vitamin c in smokers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

male smoker health

Exclusion criteria:

systemic disease history of chemotherapy or radiotherapy take any medications continuously during the past 3 months have nephrolithiasis take alcohol and supplements oral pathology based on clinical examination

Age

From **25 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Table of random numbers

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 Rafsanjan University of Medical Sciences

Street address

Building No. 3, Central Department of Rafsanjan University of Medical Science, Emam Ali Blvd.

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2017-03-12, 1395/12/22

Ethics committee reference number

IR.RUMS.REC.1396.58

Health conditions studied

1

Description of health condition studied

total anti oxidant capacity

ICD-10 code

Z00

ICD-10 code description

Encounter for general examination without complaint, suspected or reported diagnosis

Primary outcomes

1

Description

total antioxidant capacity in healthy smokers

Timepoint

at the beginning of study and 20 days after taking vitamin c

Method of measurement

total anti oxidant capacity assay kits

Secondary outcomes

1

Description

salivary total antioxidant capacity

Timepoint

At the beginning of study and 20 days after receive vitamin c

Method of measurement

Total antioxidant capacity assay kits

Intervention groups

1

Description

Intervention group: 1000 mg boiling tablets of vitamin c each day for 20 days

Category

Treatment - Drugs

2

Description

Intervention group: 500mg boiling tablets of vitamin c each day for 20 days

Category

Treatment - Drugs

3

Description

Control group: receive no placebo

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school of Rafsanjan university of medical sciences

Full name of responsible person

Nazanin Kamyab

Street address

Dental school, West Sahid Mofateh Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717931136

Email

nazaninkamyab@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Atekeh Movaghari Pour

Street address

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Fax

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Email

dentistry@rums.ac.ir

Web page address

<http://dentistry.rums.ac.ir>

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

Yes

Title of funding source

Rafsanjan University of Medical Sciences

Proportion provided by this source

100

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Nazanin Kamyab

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Nazanin Kamyab

Position

Assistant Professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

access to all data

When the data will become available and for how long

Getting started from 2018

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

No other conditions required

From where data/document is obtainable

nazanin.kamyab@rums.ac.ir

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

Having an organizational email and verification of the title and code of ethics recorded

Comments