

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the systemic use of Lycopene supplementation on non-surgical periodontal treatment

Protocol summary

Study aim

Determining the effect of systemic use of the lycopene antioxidant in the non-surgical treatment of periodontitis

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 42 patients. Random allocation software version 1.0 under Windows was used for randomization.

Settings and conduct

42 Patients with periodontitis stage II to IV and grade B referred to Yazd Dental Faculty in 1402 will be selected. demographic characteristics, medical and dental history, probe depth, amount of loss of adhesion, bleeding index is recorded at the time of examination. They will receive hygiene education and supra and subgingival SRP using manual and ultrasonic devices. Patients are divided into two groups of 21 people. The test group received 400mg lycopene M Plus (Perarin Pars Company) once a day and the control group received the placebo capsule with the same pattern for 2 months. After a month, patients will be examined for periodontal status and how to take the supplement, and at the end of 2 months (to record all the variables of probe depth, adhesion loss and gingival bleeding index) The patient and the person recording the indicators before and after the study do not know the type of drug received (2-blind). The distribution of placebo capsules in the same bottles was done by the pharmacist and coded as A (case group) and B (control group). Then it will be given to a specialized assistant.

Participants/Inclusion and exclusion criteria

To conduct this study, patients referred to Yazd Dental School in 1402 were screened and patients who, according to the guidelines of the American Academy of Periodontology in 2017, have periodontitis stage II (moderate periodontitis) to IV (extensive periodontitis) with significant loss of teeth) and grade B, will be selected.

Intervention groups

Lycopene

Main outcome variables

Decrease in CAL, PD and BI in intervention group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230830059303N1**

Registration date: **2023-09-09, 1402/06/18**

Registration timing: **prospective**

Last update: **2023-09-09, 1402/06/18**

Update count: **0**

Registration date

2023-09-09, 1402/06/18

Registrant information

Name

Faezeh Sadeghi Heris

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 766 2640

Email address

sdgh.f4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the systemic use of Lycopene supplementation on non-surgical periodontal treatment

Public title

Evaluation of the systemic use of Lycopene supplementation on non-surgical periodontal treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

the patient is systematically healthy CAL is more than 3 mm and clinical signs of gingivitis such as erythema and BOP are present. The patient should not smoke cigarettes or other types of tobacco products. The patient does not have any history of periodontal treatment in the last 6 months. Absence of disease or systemic conditions that interfere with wound healing. Absence of inflammatory conditions in the oral mucosa such as aphthous ulcers and lichen planus and acute allergic reactions Not using drugs that affect periodontium (anticonvulsants, calcium channel blockers and immunosuppressors) Not taking antioxidant supplements such as Vitamin C or melatonin Not allergic to tomatoes The patient should not be treated with radiotherapy etc. Not being pregnant or breastfeeding or not receiving hormonal drugs Not taking anti-inflammatory drugs such as ibuprofen and...

Exclusion criteria:

Non-attendance of the patient in the follow-up sessions Failure to follow instructions for taking oral lycopene supplements Failure to observe oral hygiene

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

For random sampling, first, using the Random allocation software version 1.0 under Windows, we generate a random sequence using a simple random allocation method. In this table, we specify from 1 to 42 and each number is assigned to an intervention group (A or B). Number 1 is assigned to the first qualified person, second person is assigned number 2, and so on up to 42 patients. In order to blindly assign clients randomly, we ask for the help of a third person who is unaware of the interventions and this table is given to him. and assigning the person to one of the groups is determined

and carried out.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the person recording the indicators before and after the study do not know the type of drug received (lycopene or placebo) (2-blind). The distribution of placebo capsules in the same bottles was done by the pharmacist and coded as A (case group) and B (control group). Then it will be given to a specialized assistant.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yazd University of Medical Sciences

Street address

Dr. Asadi pharmacy, second Sarvestan , Shahrak shahid beheshti, Babayi Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1651137543

Approval date

2023-07-22, 1402/04/31

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1402.027

Health conditions studied**1****Description of health condition studied**

chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes**1****Description**

clinical attachment level

Timepoint

baseline , 4weeks and 8 weeks after using supplement

Method of measurement

periodontal probe

2

Description

periodontal pocket depth

Timepoint

baseline, 4weeks and 8 weeks after using supplement.

Method of measurement

periodontal probe

3

Description

bleeding index

Timepoint

baseline, 4weeks and 8 weeks after using supplement.

Method of measurement

percentage of bleeding sites

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lycopene

Category

Treatment - Drugs

2

Description

Control group: placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontics department of Shahid Sadoughi
Dentistry faculty of Yazd

Full name of responsible person

Faezeh Sadeghi Heris

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Dr. Asadi pharmacy, second Sarvestan , Shahrak
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Ali Asghar Ebrahimi

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Department of Environmental Health, School of Public
Health Environmental Science and Technology
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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Faezeh Sadeghi Heris

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

Part of the data related to the main outcome is shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments