Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+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 Shaid Beheshti, Babayi Highway, Tehran
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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
Street address
Department of Environmental Health, School of Public Health Environmental Science and Technology Research Center Shahid Sadoughi University of Medical Sciences
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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
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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