Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of resveratrol supplementation on clinical parameters and inflammatory markers in diabetic patients with chronic periodontitis

Protocol summary

Study aim

Determining the effect of resveratrol supplementation on periodontal status and inflammatory markers in diabetic patients with chronic periodontitis

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 52 patients. The random assignment of samples to the intervention and control groups will be randomly stratified (stratified randomization).

Settings and conduct

Non-surgical periodontal treatment will be performed for 52 diabetic patients with moderate to severe chronic periodontitis (26 case group, 26 control group) and for 4 weeks, one capsule of 600 mg of resveratrol will be given to the case group and control group patients They will receive 600 mg placebo tablets containing starch every day. All clinical parameters will be measured 4 weeks and 3 months after the intervention in recalling the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 30-60 years, body mass index 18.5 to 30 kg/m2, patients with confirmed diabetes mellitus controlled HBA1C>9, and moderate to severe periodontal disease. Exclusion criteria: non-cooperation, kidney failure, systemic disease, drug use, pregnancy and breastfeeding, smoking, allergy to black grapes or blueberries.

Intervention groups

Non-surgical periodontal treatment will be performed for 52 diabetic patients with moderate to severe chronic periodontitis (26 case group, 26 control group) and for 4 weeks, one capsule of 600 mg of resveratrol will be given to the case group and control group patients They will receive 600 mg placebo tablets containing starch every day. All clinical parameters will be measured 4 weeks and 3 months after the intervention in recalling the patients.

Main outcome variables

Probing depth, clinical attachment level, plaque index, bleeding index, and the amount of IL-8 and IL-1β in saliva.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171015036782N9**
Registration date: **2023-02-14, 1401/11/25**
Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**
Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name
farzane vaziri
Name of organization / entity
Shahid sadoughi dental university
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Iran (Islamic Republic of)
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Email address
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of resveratrol supplementation on clinical parameters and inflammatory markers in diabetic patients with chronic periodontitis

Public title
the effect of resveratrol on the gingival health of diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 30-60 years Body mass index (BMI) 18.5 to 30 kg/m2 Patients with confirmed and controlled diabetes mellitus (minimum one year and maximum 5 years since diagnosis) 9>HBA1C Moderate to severe periodontal disease
Exclusion criteria:
Patient non-cooperation Diabetes complications such as kidney failure No systemic disease taking medication Pregnancy and breastfeeding smoking Allergy to black grapes or blueberries
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
The selection of patients and study samples in diabetic and non-diabetic groups is done using the purposive sampling method. The random allocation of the samples to the treatment and control groups will be randomly stratified and based on age and gender (stratified randomization), which means that there will be no significant difference in the average age and gender frequency in the drug and placebo groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups. Dentists are given a table of coded numbers in advance and patients are entered into the study in the order of the numbers in the table. Therefore, the present study is double-blind. Resveratrol and placebo tablets are the same in terms of shape, color and size and are delivered to the patient in the package.
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
Shahid Bahonar square
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Province
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Postal code
۸۹۱۶۹۷۸۴۷۷
Approval date
2022-07-11, 1401/04/20
Ethics committee reference number
IR.SSU.DENTISTRY.REC.1401.032

Health conditions studied

1

Description of health condition studied
Chronic periodontitis
ICD-10 code
K05.3
ICD-10 code description
Chronic periodontitis

2

Description of health condition studied
diabetes
ICD-10 code
E14
ICD-10 code description
Unspecified diabetes mellitus

Primary outcomes

1

Description
Probing depth
Timepoint
At the beginning of the study (before the start of the intervention) and 1 month and 3 months after the start of the study
Method of measurement
With Probe Williams

2

Description
Clinical Attachment Level
Timepoint
At the beginning of the study (before the start of the intervention) and 1 month and 3 months after the start of the study
Method of measurement
With Probe Williams

3

Description
plaque index
Timepoint
At the beginning of the study (before the start of the intervention) and 1 month and 3 months after the start of the study
Method of measurement
The percentage of plaque accumulation around the surfaces of the teeth after evaluation with a revealing substance

4

Description
Bleeding index
Timepoint
At the beginning of the study (before the start of the intervention) and 1 month and 3 months after the start of the study
Method of measurement
Percentage of bleeding around all teeth after 30 seconds following probing

5

Description
IL-1β
Timepoint
At the beginning of the study (before the start of the intervention) and 1 month and 3 months after the start of the study
Method of measurement
The amount of interleukin IL-1β per unit volume of saliva

6

Description
IL-8
Timepoint
At the beginning of the study (before the start of the intervention) and 1 month and 3 months after the start of the study
Method of measurement
The amount of interleukin IL-8 per unit volume of saliva

Secondary outcomes

1

Description
HBA1C
Timepoint
At the beginning of the study (before the start of the intervention) and 1 month and 3 months after the start of the study
Method of measurement
blood test

2

Description
FBS
Timepoint
At the beginning of the study (before the start of the intervention) and 1 month and 3 months after the start of the study
Method of measurement
From the kit by the enzymatic method

3

Description
Body mass index
Timepoint
At the beginning of the study (before the start of the intervention) and 1 month and 3 months after the start of the study
Method of measurement
BMI is calculated using height and weight. BMI = weight (kilograms) / (height) 2 (square meters)

Intervention groups

1

Description
Intervention group: 26 diabetics with moderate to severe chronic periodontitis will be selected after examination and diagnosis of periodontal symptoms and according to the entry and exit criteria and after giving the required information and obtaining written consent. After evaluating the primary and secondary outcomes, non-surgical periodontal treatment will be performed for all patients, and for patients in the 4-week case group, one 600 mg capsule (from Canada's plantvital company) will be prescribed every day during the study period with all patients 3 times in They will be contacted during the week to make sure they have taken their capsules. During the study, all patients will undergo periodontal examinations and treatments, including scaling and leveling of the root surface if needed, and the necessary training for oral and dental hygiene, including the correct way of brushing and flossing, will be given to them, and at the end of the course Patients will be re-examined after 1 month and 3 months.
Category
Treatment - Drugs

2

Description
Control group: 26 diabetics with moderate to severe chronic periodontitis will be selected after examination

and diagnosis of periodontal symptoms and according to the entry and exit criteria and after giving the required information and obtaining written consent. After evaluating the primary and secondary outcomes, non-surgical periodontal treatment will be performed for all patients, and patients in the control group will receive 600 mg placebo tablets containing starch every day. Patients will be asked to take these capsules in the morning after eating breakfast. During the study period, all patients will be contacted 3 times a week to ensure that they take their capsules. During the study, all patients will undergo periodontal examinations and treatments, including scaling and leveling of the root surface if needed, and the necessary training for oral and dental hygiene, including the correct way of brushing and flossing, will be given to them, and at the end of the course Patients will be re-examined after 1 month and 3 months.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi University of Medical Sciences, Yazd
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd 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
Nazanin Roqani Dehkordi
Position
Periodontics resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Latest degree
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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
Yes - There is a plan to make this available

Title and more details about the data/document
Only a part of the data, such as the information related to the main result or the like, can be 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
It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
If periodontal and resveratrol treatments affect the severity of diabetes because by providing effective solutions to improve oral and dental health and emphasizing more on hygiene, it is possible to reduce the severity of diabetes and impose heavier costs of this disease in material terms. and spiritually prevented

From where data/document is obtainable
Conductors of the research project

What processes are involved for a request to access data/document
The request for data requires written consent from all the implementers of the research project.

Comments