

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparing the effect of Resveratrol supplementation and standard treatment on clinical parameters and inflammatory markers in the patients with chronic periodontitis

Protocol summary

Study aim

Determine the therapeutic effect of resveratrol (as adjunct therapy) on clinical parameters and inflammatory markers of saliva among chronic periodontitis patients

Design

In this double-blind study, 40 patients with moderate to severe chronic periodontitis referring to periodontics department of Shahid Sadoughi Dental School of Yazd were selected and after coding were randomly divided into intervention and control groups.

Settings and conduct

Initially, the levels of Plaque Index(PI), Clinical Attachment Loss(CAL), Probing Depth(PD), Bleeding Index(BI) and IL-8 and IL-1 β in saliva will be recorded for patients and after non-surgical periodontal treatment and receiving capsules in both groups for 4 weeks, patients will be recalled and the levels of PD, CAL, PI, BI, and the levels of IL-8 and IL-1 β in saliva will be re-evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 30 to 60 years; moderate to severe chronic periodontitis. Exclusion criteria: pregnancy, breast feeding, smoking, using immunosuppressive medications and NSAIDs, using medications that slow blood clotting; cancer under treatment

Intervention groups

non-surgical periodontal treatment will be done for all the patients. The patients in intervention group will take 480 mg resveratrol capsule daily and the control patients will take 480mg placebo capsules containing starch daily.

Main outcome variables

Clinical variables: Probing depth, clinical attachment loss, plaque index, bleeding index, The levels of IL-8 and IL-1 β in saliva

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171015036782N6**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

farzane vaziri

Name of organization / entity

Shahid sadoughi dental university

Country

Iran (Islamic Republic of)

Phone

+98 35 3620 4764

Email address

f.vaziri@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparing the effect of Resveratrol supplementation and standard treatment on clinical parameters and inflammatory markers in the patients with chronic periodontitis
Public title	Effect of herbal medicine, Resveratrol, on gingival infection
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: age between 30 to 60 years old chronic moderate to severe periodontitis Exclusion criteria: Pregnancy Breast feeding Traveling for more than 2 weeks Smoking Using immunosuppressive medications Using NSAIDs Using anti hypertension drugs or Medications that slow blood clotting such as warfarin Using insulin Affecting by uterine cancer, breast cancer or ovarian cancer or being under cancer treatment Advanced kidney and liver problems Allergy to black grapes or blueberry Periodontal treatment history during the past 6 months Considerable changes in diet over the past 6 months
Age	From 30 years old to 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	- Participant - Investigator
Sample size	Target sample size: 40
Randomization (investigator's opinion)	Randomized
Randomization description	Patients are divided into control and intervention groups using a random-number table
Blinding (investigator's opinion)	Double blinded
Blinding description	In this study, the participants and the investigator will not be aware of the type of prescribed drug.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Yazd University of Medical Sciences
Street address	P4, Yas complex, Javadolaeme, Safayieh
City	Yazd
Province	Yazd
Postal code	8915839985
Approval date	2018-02-26, 1396/12/07
Ethics committee reference number	IR.SSU.REC.1396.206
Health conditions studied	
<u>1</u>	
Description of health condition studied	moderate to severe chronic periodontitis
ICD-10 code	K05.3
ICD-10 code description	Chronic periodontitis
Primary outcomes	
<u>1</u>	
Description	Probing depth
Timepoint	Beggining of study and 1 month later
Method of measurement	Williams probe
<u>2</u>	
Description	Clinical Attachment Loss
Timepoint	Beggining of study and 1 month later
Method of measurement	Using the Williams probe
<u>3</u>	
Description	Plaque Index
Timepoint	Beggining of study and 1 month later
Method of measurement	By colloring with disclosing pills and calculating the percentage of whole mouth

4

Description

Bleeding Index

Timepoint

Beggining of study and 1 month later

Method of measurement

Checking Bleeding on probing in the mouth and measuring its percentage

5

Description

The level of IL-8 in saliva

Timepoint

Beggining of study and 1 month later

Method of measurement

Eliza kit

6

Description

The level of IL-1 β in saliva

Timepoint

Beggining of study and 1 month later

Method of measurement

Eliza kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Non-surgical periodontal treatment and daily administration of resveratrol 480 mg capsule, produced by HerbaFit company (Germany) for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: non-surgical periodontal treatment and daily administration of placebo 480 mg capsule (containing starch) for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Shabnam Nikniaz

Street address

Shahid Sadoughi Faculty of Dentistry Yazd, Emam

Reza square

City

Yazd

Province

Yazd

Postal code

8915839985

Phone

+98 35 3621 2623

Email

sh.nikniaz@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Alireza Danesh Kazemi

Street address

Shahid Sadoughi Faculty of Dentistry Yazd, Imam Reza Square

City

Yazd

Province

Yazd

Postal code

8915839985

Phone

+98 35 3621 2623

Email

sh.nikniaz@gmail.com

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

Shabnam Nikniaz

Position

Post graduation student

Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
P4, Yas complex, Javadolaeme, Safayieh
City
Yazd
Province
Yazd
Postal code
8915873948
Phone
+98 914 490 1929
Email
sh.nikniaz@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Shabnam Nikniaz
Position
Post graduation student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
P4, Yas complex, Javadolaeme, Safayieh
City
Yazd
Province
Yazd
Postal code
8915873948
Phone
+98 914 490 1929
Email
sh.nikniaz@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Shabnam Nikniaz
Position
Post graduation student

Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
P4, Yas complex, Javadolaeme, Safayieh
City
Yazd
Province
Yazd
Postal code
8915873948
Phone
+98 914 490 1929
Email
sh.nikniaz@gmail.com

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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

The whole data is shared

When the data will become available and for how long

Six months after the publication of the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Email, Call

From where data/document is obtainable

Shabnam Nikniaz, 09144901929, sh.nikniaz@gmail.com

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

After sending the Email, the data will be transmitted

Comments