ISRCTN10684944 https://doi.org/10.1186/ISRCTN10684944

Effect of resveratrol on periodontal disease in an aging adult population

Submission date	**Recruitment status**	[_] Prospectively registered
15/03/2025	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/04/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/04/2025	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Aging is associated with the development of various diseases, including periodontal disease (PD). The prevalence of PD increases in the fifth decade of life and increases with advancing age, occurring in more than 50% of cases in old age. PD is a chronic inflammatory disorder of the entire periodontium, which can irreversibly destroy the tissue surrounding the tooth and cause alveolar bone resorption. Therefore, if not diagnosed and treated promptly, tooth loss will occur. PD is also a significant risk factor for systemic diseases such as cardiac endocarditis and Alzheimer's disease, among others.

The pathophysiology of PD begins with the colonization of specific bacteria and an acute inflammatory process, coupled with an increase in reactive oxygen species (ROS). When periodontal cells are exposed to prolonged exposure to high concentrations of ROS and the amount of antioxidants decreases, oxidative stress (OS) occurs, which causes damage to a wide variety of molecules, including lipids, proteins, enzymes, and DNA, resulting in tissue damage. Furthermore, when pathogenic bacteria in the gingival sulcus continue to spread and the acute immune response is insufficient, the inflammatory response becomes chronic and inefficient. This event triggers the production of inflammatory mediators that cause the destruction of alveolar bone and soft tissues.

In this context, in addition to prevention through good oral hygiene, dental checkups, and prophylaxis every 6 months, some alternatives have been proposed with nutraceutical supplements such as resveratrol, for preventive and therapeutic adjuvant purposes; however, studies are scarce and inconclusive, hence the importance of continuing this line of research.

In this sense, resveratrol, a polyphenol found in grapes and berries, has antioxidant, anti-inflammatory, hepatoprotective, neuroprotective, anticancer, and antidiabetic properties, in addition to being safe for human consumption.

Preclinical studies show promising results in the treatment of PD with resveratrol; however, as noted, clinical trials are still scarce and controversial. Therefore, the purpose of this study is to determine the effect of resveratrol consumption on the clinical course of PD in aging individuals.

Who can participate?

A triple-blind, randomized clinical trial will be conducted with a convenience sample of 60 people

aged 45 to 59, residing in Mexico City, with a clinical diagnosis of PD, of either sex, and without smoking or alcoholism, or taking antioxidants or hormone replacement therapy, in the case of women.

What does the study involve?
The sample will be randomly divided into two groups: (i) experimental, which will receive two capsules containing 500 mg of resveratrol daily for 6 months, and (ii) placebo, which will receive a capsule identical in appearance to the other groups daily for 6 months.

What are the possible benefits and risks of participating?
Benefits
The tests performed and the resveratrol will be free of charge. The results of the oral examination, blood chemistry, lipid profile, kidney profile, complete blood count, and glycosylated hemoglobin will be given to participants for monitoring and evaluation of their health status. In addition, all participants will receive dental prophylaxis upon inclusion in the study.
Risks
Although resveratrol has been shown to be safe and approved for use in humans and poses no health risks, it may cause stomach upset in some sensitive individuals. If you are assigned to the placebo group, taking the placebo poses no risk. The oral examination and blood sample collection will be performed by experienced personnel using new, disposable equipment.

Where is the study run from?
Faculty of Higher Studies Zaragoza, National Autonomous University of Mexico

When is the study starting and how long is it expected to run for?
Project planning began on July 15, 2021. Recruitment of the population began on October 24, 2022, and will end on November 28, 2025. After that, the final results are expected to be obtained no later than May 31, 2026. Therefore, the project is expected to last approximately three and a half years.

Who is funding the study?
Support will be provided by the General Directorate of Academic Personnel Affairs (DGAPA), Research and Technological Innovation Project Support Program (PAPIIT), with folio IA209723.

Who is the main contact?
PhD. Beatriz Hernández-Monjaraz
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
IA209723

Study information

Scientific Title
Effect of resveratrol on markers of oxidative stress and chronic inflammation and the clinical course of periodontal disease in an aging adult population

Study objectives
Considering the scientific reports regarding the effectiveness of resveratrol intake on PD and its antioxidant and anti-inflammatory properties, we assume that oral administration of resveratrol will improve the blood concentration of markers of oxidative stress and chronic inflammation, as well as the clinical course of PD in patients undergoing aging.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/07/2021, Ethics Committee of the Faculty of Higher Studies Zaragoza, UNAM (Batalla 5 de Mayo S/N, Ejército de Oriente Zona Peñón, Iztapalapa, Mexico City, 09230, Mexico; +55 5623 0724; etica.enlace@zaragoza.unam.mx), ref: FESZ/DEPI/CE/014/21

Primary study design
Interventional

Study design
Single-centre Interventional triple-blinded randomized controlled trial

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Treatment of periodontal disease in an aging adult population

Interventions
All participants will be given a prophylaxis and will be randomly assigned to two study groups: i) the experimental group, which will receive a capsule with 500 mg of resveratrol every 12 hours, daily for 6 months, and ii) the placebo group, which will receive an identical-looking capsule. Since this will be a triple-blind randomized clinical trial, the researcher, the patients, and the analyst will not be aware of the treatment or placebo they will take.

Participants will be randomly divided into two groups via the block randomization method designed using R program, which randomly distributes participants into two random permuted blocks, each containing 30 participants with an allocation ratio of 1:1. To achieve allocation concealment, randomization, and allocation will be performed before the commencement of the trial by a third party (a research student unaware of the study details).
All analyses will be performed using the R program (2024). R Core Team. R: A Language and Environment for Statistical Computing. v4.4.0 (Version 4.4.0), R Foundation for Statistical Computing, October 10, 2024.

Intervention Type
Supplement

Primary outcome(s)
1. The effect of resveratrol on the clinical course of PD will be assessed by periodontal pocket depth, gingival index, and radiographs in aging adults with periodontal disease, at baseline, 3 and 6 months.
2. The effect of resveratrol on blood concentration of oxidative stress markers through measurement of isoprostanes, DNA damage, total antioxidant activity and the antioxidant capacity of the enzymes superoxide dismutase (SOD) and glutathione peroxidase (GPx) in adults with periodontal disease in the process of aging, at baseline, 3 and 6 months.
3. The effect of resveratrol on blood concentration of chronic inflammation markers through measurement of IL-1β, IL-6, IL-8, IL-10, IL-12p70 and TNF-α in an aging adult population with periodontal disease, at baseline, 3 and 6 months.

Key secondary outcome(s)
Measured using on automated equipment (Selectra Junior) and commercial kits will be used (Randox Laboratories Ltd.) at baseline, 3 and 6 months:
1. Fasting glucose
2. Glycosylated hemoglobin
3. Lipid profile (total cholesterol, triglycerides and HDL cholesterol)
4. Renal profile (urea, uric acid and creatinine)

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. People aged 45 to 59 years
2. Residence in Mexico City
3. Clinical diagnosis of periodontal disease
4. The patient must sign (or fingerprint) the informed consent letter.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
45 Years

Upper age limit
59 Years

Sex
All

Key exclusion criteria
1. No occlusal trauma
2. No complete edentulousness
3. No smoking
4. No alcoholism
5. No antioxidant intake
6. No hormone replacement therapy

Date of first enrolment
15/08/2022

Date of final enrolment
28/11/2025

Locations

Countries of recruitment
Mexico

Study participating centre
Faculty of Higher Studies Zaragoza, National Autonomous University of Mexico
Av. Guelatao 66 Ejército de Oriente, Iztapalapa
Mexico City
Mexico
09230

Sponsor information

Organisation
National Autonomous University of Mexico

Funder(s)

Funder type
University/education

Funder Name
Dirección General de Asuntos del Personal Académico, Universidad Nacional Autónoma de México (DGAPA, UNAM), PAPIIT IA209723

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Hernández-Monjaraz Beatriz, beatrizhmonjaraz@hotmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Spanish		17/04/2025	No	Yes
Protocol file	in Spanish		17/04/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes