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Use of zinc and magnesium as a supplement to non-surgical periodontal treatment in patients with type 2 diabetes mellitus

Submission date
01/09/2023

Recruitment status
No longer recruiting

Registration date
13/09/2023

Overall study status
Completed

Last Edited
22/07/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Periodontal disease (PD) associated with type 2 diabetes mellitus (DM2) is a chronic systemic condition that affects the structures supporting the teeth. Poor blood sugar control in DM2 patients contributes to the development of more severe PD, leading to systemic inflammation and the development of other diabetic complications. Recently, deficiencies in magnesium and zinc have been reported in patients with PD-DM2. It has been described that these elements play a role in regulating the inflammatory process as well as in the recovery and healing of periodontal tissues.
Non-surgical periodontal treatment (NSPT) is the gold standard for managing periodontal disease. This involves mechanical instrumentation of the root surfaces to reduce the factors contributing to the development of PD. Clinical practice guidelines for PD management have suggested the use of complementary treatments alongside non-surgical periodontal treatment to reduce clinical parameters of the disease, achieve remission, and stabilize periodontal tissues. The use of magnesium and zinc as supplements to non-surgical periodontal treatment has not been reported.
Therefore, the aim of this study is to evaluate the effects of NSPT combined with oral supplementation of magnesium oxide and zinc gluconate for 30 days on clinical periodontal characteristics, oxidative stress, and antioxidant enzymes compared to those who received only NSPT.

Who can participate?
Patients aged 18-60 years with periodontal diseases associated with type 2 diabetes mellitus

What does the study involve?
Patients who visited the department for the first time to receive periodontal treatment were assessed clinically and blood samples were taken. NSPT and oral supplementation with magnesium oxide and zinc gluconate were started weekly for 30 days. After the interventions, another clinical periodontal assessment and blood sample collection were performed.

What are the possible benefits and risks of participating?
It is expected that this treatment will help improve oral and systemic health conditions by reducing oxidative stress and increasing antioxidant enzymes. Possible risks of NSPT included pain, inflammation, and bleeding in the intervention area. Regarding the use of supplements, the risks included diarrhea, headache, stomach pain, and vomiting.

Where is the study run from?
Centro de Alta Especialidad Dr. Rafael Lucio (México)

When is the study starting and how long is it expected to run for?
May 2018 to June 2023

Who is funding the study?
1. Consejo Nacional de Humanidades, Ciencia y Tecnología (CONAHCYT) (Mexico)
2. Institute of Health Sciences, Universidad Veracruzana (Mexico)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SIREI-164402023120

Study information

Scientific Title
The effects of non-surgical periodontal treatment plus zinc and magnesium supplementation on oxidative stress and antioxidant enzymes in type 2 diabetes patients

Study objectives
It has been proposed as a hypothesis that supplementation with Zn and Mg as complements to non-surgical periodontal treatment supports the improvement of periodontal clinical conditions through the regulation of oxidative stress and the increase of antioxidant enzymes superoxide dismutase and catalase

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/10/2018, The research ethics committee of the Institute of Health Science from Veracruzana University (Av Luis Castelazo Ayala S/N Industrial Ánimas, Xalapa, Veracruz, 91190, Mexico; +52 (0)2288426233; ceiics@uv.mx), ref: No. 010/2022

Study design
Quasi-experimental study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment for periodontal diseases in type 2 diabates patients

Interventions

The control group received non-surgical periodontal treatment and oral physiotherapy for 30 days (n = 19). The experimental group received non-surgical periodontal treatment plus 50 mg of zinc gluconate and 500 mg of magnesium oxide in oral administration for 30 days (n = 20).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Clinical periodontal parameters such as deep on probing, clinical attachment level, bleeding on probing, and periodontal inflamed surface area, measured using periodontogram at baseline and 30 days after treatment
2. Biochemical parameters such as glucose levels, zinc levels, magnesium levels, total cholesterol levels, triglycerides levels, HDL-C, and LDL-C, measured using biochemical analyses at baseline and 30 days after non-surgical periodontal treatment

Key secondary outcome(s))
1. Oxidative stress measured using lipoperoxidation reaction and MDA levels at baseline (day 0) and 30 days after the interventions
2. Antioxidant enzymes measured using commercial kits (superoxide dismutase and catalase levels) at baseline (day 0) and 30 days after the interventions

Completion date
23/06/2023

Eligibility

Key inclusion criteria
1. Patients with periodontal diseases associated with type 2 diabetes mellitus
2. Males and females
3. Aged 18-60 years
4. Accepted to participate in the research
5. Patients under medical surveillance
6. Patients who attended the periodontia service at an established time period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
39

Key exclusion criteria
1 Patients with hypersensitive to zinc and magnesium supplements
2. Patients with prior non-surgical periodontal treatment
3. Patients who consumed antibiotics, steroids, and central nervous system (CNS) depressants

Date of first enrolment
30/11/2018

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
Mexico

Study participating centre
Centro de Alta Especialidad Dr. Rafael Lucio.
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Study participating centre
Laboratorio de Medicina Traslacional , Universidad Veracruzana
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Sponsor information

Organisation
Universidad Veracruzana

ROR
https://ror.org/03efxn362

Funder(s)

Funder type
University/education

Funder Name
Consejo Nacional de Ciencia y Tecnología

Alternative Name(s)
Consejo Nacional de Humanidades, Ciencias y Tecnologías, Consejo Nacional de Ciencia y Tecnología, National Council of Humanities, Sciences and Technologies, Mexican National Council of Science and Technology, National Council for Science and Technology (CONACyT), National Council of Science and Technology, Mexico, Conahcyt

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Mexico

Funder Name
Universidad Veracruzana

Alternative Name(s)
University of Veracruz, UV

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Mexico

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated in this research was stored in the repository of the Institute of Health Sciences at the University of Veracruz. This dataset would be available for review through a prior

request to cgogeascoechea@uv.mx. This request would be evaluated by the corresponding institutional authorities. Participant data includes information from 45 patients (clinical history, a data collection instrument, sociodemographic data).

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/08/2024	22/07/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes