

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

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| Submission date 01/09/2023 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 13/09/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 22/07/2025 | Condition category Oral Health | <input type="checkbox"/> 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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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Dental clinic, Hospital, Laboratory, Medical and other records

Study type(s)

Treatment

Participant information sheet

Not applicable

Health condition(s) or problem(s) studied

Treatment for periodontal diseases in type 2 diabetes 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 measure

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

Secondary outcome measures

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

Overall study start date

18/05/2018

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

45

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.

Av. Adolfo Ruíz Cortines N° 2903, unidad magisterial

Xalapa, Veracruz

Mexico

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Study participating centre

Laboratorio de Medicina Traslacional , Universidad Veracruzana

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Organisation

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Sponsor type

University/education

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<https://ror.org/03efxn362>

Funder(s)

Funder type

University/education

Funder Name

Consejo Nacional de Ciencia y Tecnología

Alternative Name(s)

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

Publication and dissemination plan

The results of this research were shared in specialized forums within the dental field. Likewise, there is an intention to publish them in a high-impact international scientific journal, peer-reviewed.

Intention to publish date

30/09/2023

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 cgogeoascoechea@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 |