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Evaluation of the effect of choline-stabilized orthosilicic acid in patients with gingivitis

Submission date
02/02/2026

Recruitment status
Recruiting

Registration date
18/02/2026

Overall study status
Ongoing

Last Edited
16/02/2026

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and aims
Gingivitis is the earliest and reversible form of gum disease, resulting in mild symptoms such as irritation, redness, and inflammation of the gums, as well as bleeding upon gentle probing. Gingivitis is commonly induced by the accumulation of plaque on the teeth, resulting in a bacterial infection of the gums, but non-plaque-induced forms of gingivitis caused by systemic diseases are possible as well. When untreated, gingivitis can develop into periodontitis, resulting in damage to the soft tissues and bone surrounding the teeth.
A previous clinical study indicated that choline-stabilized orthosilicic acid may have a preventive role in the development of periodontitis.
This study will investigate whether choline-stabilized orthosilicic acid can improve the symptoms of gingivitis.

Who can participate?
Adults between the ages of 18 and 75 years with generalized gingivitis symptoms.

What does the study involve?
Patients are randomly allocated to either receive choline-stabilized orthosilicic acid or placebo (dummy capsule). All patients will be instructed to take two capsules daily for 6 months. Assessments will be done at the screening visit, inclusion in the study, and after 1, 3, and 6 months of treatment.

What are the possible benefits and risks of participating?
Choline-stabilized orthosilicic acid may improve gingivitis symptoms. Considering the available information about choline-stabilized orthosilicic acid, there are no foreseeable risks to human health when used as instructed.

Where is the study run from?
1. Bio Minerals NV (Belgium)
2. Dental clinic, UMC Ljubljana (Slovenia)
3. Department of Periodontology, Faculty of Dentistry, Cukurova University (Turkey)
4. Campus Universitário, Egas Moniz School of Health & Science (Portugal)

When is the study starting and how long is it expected to run for?
April 2025 to June 2027

Who is funding the study?
Bio Minerals NV (Belgium)

Who is the main contact?
Prof. Dr. Rok Gašperšič, Ph.D, rok.gaspersic@kclj.si

Contact information

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Principal investigator

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Additional identifiers

Study information

Scientific Title
A randomized, double-blind, placebo-controlled study to assess the effect of choline-stabilized orthosilicic acid on gingivitis

Study objectives
The aim of the study is to evaluate the effect of oral intake of choline-stabilized orthosilicic acid on generalized gingivitis compared to placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/12/2024, National Medical Ethics Committee of Slovenia (Štefanova ulica 5, Ljubljana, 1000, Slovenia; +386 (0)1 478 69 06; gp.mz@gov.si), ref: 0120-492/2024-2711-4

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Generalized dental plaque-induced gingivitis

Interventions
Participants are randomized to either the placebo or active treatment group (choline-stabilized orthosilicic acid [CS-OSA]) using block randomization in a ratio of 1:1.

All participants will be instructed to take daily for 6 months, two capsules orally of either placebo (520 mg microcrystalline cellulose beadlets per capsule) or the active ingredient (520 mg beadlets containing 5 mg of silicon and 100 mg of choline in the form of choline-stabilized orthosilicic acid per capsule, Bio Minerals NV). The trial starts with a screening visit and a wash-out period during which the use of treatment for gingivitis is not permitted.

Assessments will be done respectively at screening, at inclusion (baseline), and after 1, 3 and 6 months of treatment.

Intervention Type
Supplement

Primary outcome(s)
1. Bleeding on probing (BOP) measured using periodontal probing at 6 sites per tooth at 6 months after treatment (baseline, T0 visit)

Key secondary outcome(s)
1. BOP measured using periodontal probing at 6 sites per tooth at screening, baseline, and 1 and 3 months after treatment (baseline, T0 visit)

2. Gingival index (GI) measured using Löe and Silness Index at 2 sites per tooth at screening, baseline, and 1, 3 and 6 months after treatment (baseline, T0 visit)

3. Probing pocket depth (PPD) measured using periodontal probing at 6 sites per tooth at screening, baseline, and 1, 3 and 6 months after treatment (baseline, T0 visit)

4. Full mouth plaque score (FMPS) measured using periodontal probing at 6 sites per tooth at screening, baseline, and 1, 3 and 6 months after treatment (baseline, T0 visit)

5. Gingival recession (REC) measured using periodontal probing at 6 sites per tooth at screening, baseline, and 1, 3 and 6 months after treatment (baseline, T0 visit)

6. Bone formation measured using levels of biomarkers of bone formation in serum, urine, and saliva samples at baseline and 3 and 6 months after treatment (baseline, T0 visit)

7. Inflammation measured using levels of biomarkers of inflammation in serum, urine, and saliva samples at baseline and 3 and 6 months after treatment (baseline, T0 visit)

8. Oral health-related quality of life measured using the Oral Health Impact Profile questionnaire (OHIP-14) at baseline and 1, 3 and 6 months after treatment (baseline, T0 visit)

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Provision of written informed consent
2. Healthy, non-institutionalized males and females between the ages of 18 and 75 years old
3. Females must use an approved form of birth control or be postmenopausal or surgically sterile
4. A minimum of 3 natural teeth in every quadrant
5. Patients with generalized gingivitis, characterized by a BOP ≥30%

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patient is unable to understand the study procedures and/or not having given written informed consent and/or not wishing to participate in one of the subsequent therapeutic intervention protocols
2. Poor general health interfering with compliance or assessment
3. Unlikely to co-operate fully in the study
4. Participating in another clinical trial in the last 90 days
5. Pregnancy or breastfeeding
6. Smoking or history of smoking (less than 6 months prior to the start of the study)
7. Patients with poorly controlled diabetes
8. Osteonecrosis of the jaw
9. Spontaneous bleeding of the gums
10. Documented history of periodontitis
11. Patient has more than 5 crowns
12. Recent or current alcohol abuse (consumption levels of more than 28 units per week) and drug abuse
13. Subjects with documented, active infectious diseases (including but not limited to HIV, hepatitis B/C)
14. Clinically significant medical abnormalities which would make the subject unsuitable for the study as judged by the investigator
15. Patient has renal failure, documented history of stroke, myocardial infarction, or cancer
16. Non-plaque induced gingival diseases:
16.1. Hereditary gingival fibromatosis
16.2. Infection of bacterial, viral or fungal origin resulting in non-plaque-induced gingival lesions
16.3. Inflammatory and auto-immune conditions such as Crohn’s disease, plasma cell gingivitis, etc
16.4. Vitamin C deficiency
16.5. Traumatic lesions such as toothbrushing-induced gingival ulceration or chemical injuries
17. Concomitant and previous medication:
17.1. Concomitant and previous treatment with systemic antibiotics within 3 months of the start of the study
17.2. Concomitant treatment with local antiseptic, i.e. rinsing solutions to disinfect the mouth (i. e. Hextril/Hexiditine, Corsodyl/chlorhexidine-digluconate)
17.3. Concomitant and previous supplementation with food supplements containing horsetail extract, bamboo extract, silicic acid or silanol derivatives within 3 months of the start of the study
17.4. Less than 3 months between the extraction of teeth and the start of the study
17.5. No other periodontal treatment is allowed during the course of the study

Date of first enrolment
17/04/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Portugal

Slovenia

Türkiye

Study participating centre
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Study participating centre
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Sponsor information

Organisation

Bio Minerals NV

Funder(s)

Funder type

Funder Name
Bio Minerals NV

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available