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Evaluation of the effect of choline-stabilized orthosilicic acid (CS-OSA) on osseointegration and the prevention of peri-implantitis

Submission date 13/01/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 15/01/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 06/02/2026	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Dental implants are a widely used and effective solution for tooth replacement, with high long-term survival rates. Nevertheless, inflammatory conditions around osseointegrated implants are common. When inflammation is confined to the peri-implant soft tissues it is referred to as peri-implant mucositis, whereas peri-implantitis additionally involves progressive loss of supporting bone. Five to ten years after implant placement, up to one in five patients may develop peri-implantitis, and currently no gold standard exists for its prevention.

Silicon is an essential trace element implicated in bone formation and connective tissue health. Orthosilicic acid (OSA) is the bioavailable form of silicon, but its instability limits its use. Choline-stabilized orthosilicic acid (CS-OSA) is a proprietary, stable, and bioavailable form of silicon that has been shown to stimulate collagen synthesis and positively influence bone metabolism. Previous randomized, double-blind, placebo-controlled studies demonstrated beneficial effects of CS-OSA on bone turnover, bone mineral density, joint health, and connective tissue integrity. Moreover, an exploratory clinical study in patients with peri-implantitis suggested that CS-OSA may stabilize peri-implant bone levels and support mucosal tissue healing following surgical treatment.

Based on these findings, systemic supplementation with CS-OSA may contribute to improved osseointegration of dental implants and reduce the risk of peri-implant tissue breakdown and bone loss.

This study will investigate the long-term effect of oral CS-OSA supplementation on the osseointegration of newly placed dental implants and on the prevention of peri-implantitis and associated peri-implant bone loss in comparison with placebo.

Who can participate?

Adults between the ages of 18 and 75 years for whom placement of a dental implant is required.

What does the study involve?

Participants are randomly allocated to receive either CS-OSA or a placebo in a double-blind manner. Study supplementation starts one month before implant placement and continues for a total duration of 41 months. All participants receive a dental implant and standard dental care

according to clinical guidelines.
Clinical, radiographic and stability assessment of the implant and surrounding tissues are performed at regular intervals after implant, abutment and crown placement, up to 36 months after placement of the crown. These assessments include measurement of implant stability, gum health, bone levels and participant-reported quality of life.

What are the possible benefits and risks of participating?
CS-OSA may support implant integration, help maintain healthy peri-implant tissues and reduce the risk of peri-implantitis. Based on available safety data, there are no foreseeable risks to human health when CS-OSA is used as instructed.

Where is the study run from?
Bio Minerals NV (Belgium). Department of Periodontology, Faculty of Dentistry, Cukurova University (Turkey)

When is the study starting and how long is it expected to run for?
February 2026 to January 2031

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

Who is the main contact?
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Study information

Scientific Title
A randomized, double-blind, placebo-controlled study to assess the long-term effects of choline-stabilized orthosilicic acid (CS-OSA) on osseointegration and the onset of peri-implantitis

Acronym
20/2

Study objectives
The aim of the study is to evaluate the effect of long-term oral intake of choline-stabilized orthosilicic acid on osseointegration of newly placed dental implants and on the incidence of peri-implantitis compared to placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 31/08/2023, Çukurova University Ethics Committee (Çukurova University Balcali, Adana, 01330, Türkiye; +90 (0)322 338 67 22; neclaetikkurul@gmail.com), ref: 38310148/91

2. approved 26/11/2024, Çukurova University Clinical Research Ethics Committee (Cankaya, Ankara, 06520, Türkiye; +90 (0)312 218 30 00; halkla.iliskiler@titck.gov.tr), ref: 23-AKD-245

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Peri-implantitis

Interventions
Subjects are randomized to either the placebo or active treatment group (choline-stabilized orthosilicic acid) using block randomization in a ratio of 1:1.
All subjects will be instructed to take daily for 41 months, 2 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 orthosilic acid per capsule). The trial starts with a screening visit and a wash-out period during which the use of peri-implantitis treatment is not permitted.
Assessments will be done respectively at inclusion (pre-baseline) and after 1, 4, 5, 11, 17, 23, 29, 35 and 41 months of treatment.

Intervention Type
Supplement

Primary outcome(s)
1. The incidence of peri-implantitis defined as “bone loss of 3 or more than 3 mm apical of the most coronal portion of the intraosseous part of the implant and PPD of more than 4 mm with bleeding on probing or pus on probing” measured using intra-oral periapical radiographic measurements around the implant and periodontal probing at 24 months after placement of the crown (baseline, T0 visit) on the newly placed implant(s)

Key secondary outcome(s))
1. The incidence of peri-implantitis defined as “bone loss of 3 or more than 3 mm apical of the most coronal portion of the intraosseous part of the implant and PPD of more than 4 mm with bleeding on probing or pus on probing" measured using intra-oral periapical radiographic measurements around the implant and periodontal probing at 6, 12, 18, 30 and 36 months after placement of the crown (baseline, T0 visit) on the newly placed implant(s)

2. The incidence of peri-implant mucositis defined as “bleeding on probing or pus on probing around the implant and absence of bone loss beyond crestal bone level changes resulting from initial bone remodeling” measured using periodontal probing and intra-oral periapical radiographic measurements around the implant at 6, 12, 18, 24, 30 and 36 months after placement of the crown (baseline, T0 visit) on the newly placed implant(s)

3. The Periotest Value (PTV), or change in PTV measured using the Periotest device at placement of the abutment (–T1 visit), placement of the crown (baseline, T0 visit) and at 6, 12, 18, 24, 30 and 36 months after placement of the crown on the newly placed implant(s)

4. The Implant Stability Quotient (ISQ) value, or change in ISQ measured using Resonance Frequency Analysis (RFA) at placement of the implant (–T4 visit), placement of the abutment (–T1 visit) and placement of the crown (baseline, T0 visit) on the newly placed implant(s)

5. Probing pocket depth (PPD), or change in PPD, measured using periodontal probing at implant sites at placement of the crown (baseline, T0 visit) and 6, 12, 18, 24, 30 or 36 months after placement of the crown on the newly placed implant(s)

6. Gingival recession (REC), or change in REC, measured using periodontal probing at implant sites at placement of the crown (baseline, T0 visit) and 6, 12, 18, 24, 30 and 36 months after placement of the crown on the newly placed implant(s)

7. Clinical attachment level (CAL), or change in CAL, measured using periodontal probing at implant sites at placement of the crown (baseline, T0 visit) and 6, 12, 18, 24, 30 or 36 months after placement of the crown on the newly placed implant(s)

8. Bleeding on probing (BOP), or change in BOP, measured using periodontal probing at implant sites at placement of the crown (baseline, T0 visit) and 6, 12, 18, 24, 30 and 36 months after placement of the crown on the newly placed implant(s)

9. Plaque index (PI), or change in PI, measured using the “modified Quigley and Hein Index” at implant sites at placement of the crown (baseline, T0 visit) and 6, 12, 18, 24, 30 and 36 months after placement of the crown on the newly placed implant(s)

10. The gingivitis index (GI), or change in GI, measured using the “Löe and Silness Index” at implant sites at placement of the crown (baseline, T0 visit) and 6, 12, 18, 24, 30 and 36 months after placement of the crown on the newly placed implant(s)

11. Bone parameters (including bone loss, density and quality) measured using cone beam computed tomography (CBCT) and intra-oral periapical radiographic measurements at screening, after placement of the implant (–T4 visit), placement of the abutment (–T1 visit), placement of the crown (baseline, T0 visit) and 6, 12, 18, 24, 30 and 36 months after placement of the crown on the newly placed implant(s)

12. The loss of implants measured using clinical assessment at 6, 12, 18, 24, 30 or 36 months after placement of the crown (baseline, T0 visit) on the newly placed implant(s)

13. Degree of inflammation, or change in degree of inflammation, measured using clinical photographs evaluated by periodontists using a visual analogue scale (VAS; 0 = low degree of inflammation, 100 = high degree of inflammation) at placement of the crown (baseline, T0 visit) and 6, 12, 18, 24, 30 and 36 months after placement of the crown on the newly placed implant(s)

14. The participant's oral health–related quality of life, or change in quality of life, measured using the Oral Health Impact Profile questionnaire (OHIP-14) at placement of the crown (baseline, T0 visit) and 12, 24 and 36 months after placement of the crown on the newly placed implant(s)

Completion date
31/01/2031

Eligibility

Key inclusion criteria
1. Provision of written informed consent.
2. Males and Females between the ages of 18 years old and 75 years old.
3. Females must use an approved form of birth control or be postmenopausal or be surgically sterile.
4. Subjects for whom implant placement is required. If tooth extractions are needed, the extraction should be performed at least two months before implant placement.
5. Subjects who are willing to place Nucleoss T6 implants, Medentika and Dentium.
6. Placement needed of single implants with single crown.

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. Subject 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. Gingival index > 2.
7. Subjects who are not willing to place Nucleoss T6 implant, Medentika or Dentium.
8. Total edentulous subjects.
9. Exclusive placement of implant bridges.
10. Tooth extractions performed less than 2 months before implant placement.
11. Active, untreated periodontitis.
12. Previous bone augmentation procedures.
13. Subjects with documented poorly controlled diabetes (Glycated hemoglobin (HbA1c) level >6%).
14. Subjects with osteoporosis.
15. Osteonecrosis of the jaw.
16. Recent or current alcohol abuse (consumption levels of more than 28 units per week) and drug abuse.
17. Subjects with documented, active infection diseases (included but not limited to HIV, hepatitis B/C).

18. Clinically significant medical abnormalities which would make the subject unsuitable for the study as judged by the investigator.
19. Subjects with current active treatment for renal failure or cancer.
20. Subjects with documented history of stroke or myocardial infarct.
21. Concomitant and previous medication:
21.1 Concomitant and previous treatment with bisphosphonates.
21.2. Concomitant treatment with local antiseptica i.e. rinsing solutions to disinfect the mouth (i. e. Hextril/Hexiditine,
Corsodyl). Exception!: chlorhexidine-digluconate rinsing is allowed for treatment until one week after implant
placement.
21.23. 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.

Date of first enrolment
22/02/2026

Date of final enrolment
22/07/2027

Locations

Countries of recruitment
Türkiye

Study participating centre
Cukurova University, Department of Periodontology, Faculty of Dentistry
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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
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication