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Evaluation of the effect of choline-stabilized orthosilicic acid (ch-OSA®) on inflammation of the gum and bone around dental implants

Submission date
19/06/2020

Recruitment status
No longer recruiting

Registration date
24/06/2020

Overall study status
Completed

Last Edited
19/07/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims:
For many years, dental implants prove to be a good replacement when one or more teeth are missing. Although there is a high success rate of implants, problems with inflammation around implants are frequently reported. When this inflammatory process is limited to the soft tissues such as the gums around the implant, one speaks of peri-implant mucositis. Peri-implantitis is a condition where inflammation affects both the soft tissues such as the gums around the implant and the hard tissues such as the bones surrounding the implant, therefore bone loss can be a result. Five to ten years after an implant is placed, one out of five patients suffer from peri-implantitis. Currently, there is not enough evidence or studies for the recommendation of treatments or prevention measures for peri-implantitis.

Choline-stabilized orthosilicic acid was previously found to stimulate the formation of bone collagen in patients with osteopenia and to improve signs of cartilage degradation in knee osteoarthritis. The aim of this study is to investigate the effect of choline-stabilized orthosilicic acid in peri-implantitis patients.

Who can participate?
Adults between the ages of 18 and 75 years old, with documented peri-implantitis.

What does the study involve?
Patients are randomly allocated to either receive choline-stabilized orthosilicic acid or an identical dummy pill. All patients will be instructed to take 2 capsules daily for 12 months. At the start of the study, a surgical flap will be made at all peri-implantitis sites to disinfect the area of inflammation thoroughly. Assessments will be done on inclusion to the study, and after 6 and 12 months of treatment. These will involve assessment of the implant using a probe, blood samples, a CT scan, and a questionnaire on the impact on wellbeing.

What are the possible benefits and risks of participating?
The active compound, choline-stabilized orthosilicic acid, may support soft tissue healing and prevent bone loss at the peri-implantitis affected implant sites. 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?
Department of Periodontology, Faculty of Dentistry, Cukurova University (Turkey)

When is the study starting and how long is it expected to run for?
May 2016 to January 2019

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

Who is the main contact?
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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
17/1

Study information

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

Study objectives
The aim of this study is to evaluate the effect of the oral intake of choline-stabilized orthosilicic acid over a 12 month period on the clinical symptoms of peri-implantitis and associated bone loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2017, Çukurova University Ethics Committee (Balcali, Adana, 01330, Turkey; +90 (0)322 338 67 22; neclaetikkurul@gmail.com), ref: 65/4

Study design
Single-center double-blind randomized placebo-controlled phase II pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 12 months, 2 capsules orally of either placebo (520 mg microcrystalline cellulose beadlets), 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). The trial starts with a screening visit and a wash-out period during which the use of peri-implantitis treatment is not permitted.

At the start of the study (baseline) a surgical flap will be made at all peri-implantitis sites to disinfect thoroughly with EDTA. Assessments will be done respectively at inclusion (baseline), and after 6 and 12 months of treatment.

Intervention Type
Supplement

Primary outcome measure
The probing pocket depth (PPD) is measured using a calibrated probe at 6 peri-implantitis sites at baseline and 12 months

Secondary outcome measures
1. The probing pocket depth (PPD) is measured using a calibrated probe at 6 peri-implantitis sites at baseline and 6 months
2. Bleeding on probing (BOP) is measured using a calibrated probe at 6 peri-implantitis sites at baseline, 6 and 12 months
3. Gingival recession (REC) is measured using a calibrated probe at 6 peri-implantitis sites at baseline, 6 and 12 months
4. Bone gain is measured with cone-beam computed tomography (CBCT) at baseline, 6 and 12 months
5. Biomarkers of bone formation and bone resorption are measured from samples taken at baseline, 6 and 12 months
6. Serum markers of inflammation (hs-CRP) are measured from serum samples taken at baseline, 6 and 12 months
7. Patient assessment of the impact of oral health measured using the Oral Health Impact Profile (OHIP)-14 questionnaire at baseline, 6 and 12 months

Overall study start date
26/05/2016

Completion date
11/01/2019

Eligibility

Key inclusion criteria
1. Peri-implantitis, defined as bone loss of more than 3 mm measured on intra-oral radiographs and a probing pocket depth (PPD) of more than 4 mm with bleeding on probing (BOP) or pus on probing
2. Patients with single and multiple osseointegrated implants
3. Aged between 18 and 75 years
4. Use of an approved form of birth control if at risk of pregnancy
5. Provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
21

Key exclusion criteria
1. Unable to understand the study procedures 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 (≤6 months prior to the start of the study)
7. Gingival index >2
8. Active, untreated periodontitis
9. Mobile implants (i.e. complete disintegration/loss of contact of the implant with the bone)
10. Patients with poorly controlled diabetes
11. Osteonecrosis of the jaw
12. Recent or current alcohol abuse and drug abuse
13. High-risk group for HIV
14. Clinically significant medical abnormalities which would make the subject unsuitable for the study as judged by the investigator
15. Renal failure, documented history of stroke, myocardial infarct, or cancer
16. Concomitant and previous medication
16.1. Less than 6 months between the treatment with systemic antibiotics and the start of the study
16.2. Concomitant and previous treatment with bisphosphonates
16.3. Concomitant treatment with local antiseptica i.e. rinsing solutions to disinfect the mouth (i.e. Hextril/Hexetidine, Corsodyl/chlorhexidine-digluconate)

16.4. 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
14/09/2017

Date of final enrolment
15/01/2018

Locations

Countries of recruitment
Türkiye

Study participating centre
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Bio Minerals NV

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.
Participants can contact the principal investigator to get access to their raw data and for discussion.

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/09/2021	04/10/2021	Yes	No
Dataset			19/07/2023	No	No