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Evaluation of the effect of choline-stabilized orthosilicic acid (ch-OSA®) in patients with tennis elbow

Submission date
04/09/2020

Recruitment status
No longer recruiting

Registration date
15/09/2020

Overall study status
Completed

Last Edited
25/08/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Lateral epicondylitis, also known as "Tennis Elbow", is the most common overuse syndrome in the elbow. Most of the traditional treatments such as anti-inflammatory medications, rest, physical therapy and corticosteroid injections do not alter the tendon's poor healing properties. Choline-stabilized orthosilicic acid has been reported to improve the symptoms of soft tissue injuries (i.e. pain relief and improved mobility).
This study will investigate whether choline-stabilized orthosilicic acid can relieve the symptoms of epicondylitis.

Who can participate?
Adults between the ages of 18 and 70 with epicondylitis symptoms lasting 12 weeks or longer

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 20 weeks. Assessments will be done at the screening visit, inclusion to the study, and after 5, 10, 15 and 20 weeks of treatment. If necessary, rescue medication in the form of paracetamol (up to 4 g/day) is permitted up to 48 hours before the baseline visit and other study visits.

What are the possible benefits and risks of participating?
Choline-stabilized orthosilicic acid may support soft tissue healing. 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?
Bio Minerals NV (Belgium)

When is the study starting and how long is it expected to run for?
March 2017 to January 2023

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

Who is the main contact?
Prof. Dr Alexander Van Tongel
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
17/3

Study information

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

Study objectives
The aim of the study is to evaluate the effect of oral intake of choline-stabilized orthosilicic acid over a 20 week period on the symptoms of lateral epicondylitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/03/2018, Central ethical committee: Commission for Medical Ethics/Commissie voor Medische Ethiek (UZ Gent, entrance 75, route 7522, Corneel Heymanslaan 10, 9000 Gent, Belgium; +32 (0)9 332 49 62; ethisch.comite@uzgent.be), ref: not provided

Primary study design
Interventional

Study design
Multi-center double-blind randomized placebo-controlled phase III study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lateral epicondylitis

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

All participants will be instructed to take daily for 20 weeks, two 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 lateral epiconylititis treatment is not permitted.

Assessments will be done respectively at inclusion (baseline), and after 5, 10, 15 and 20 weeks of treatment. If necessary, rescue medication under the form of paracetamol (up to 4g/day) is permitted up to 48 hours before the baseline visit and other study visits.

Intervention Type
Supplement

Primary outcome(s)
Elbow pain severity measured using a visual analog scale (VAS, 100mm) at baseline and 20 weeks

Key secondary outcome(s)
1. Disabilities of the Arm, Shoulder and Hand (DASH) score measured using DASH questionnaire at baseline, 5, 10, 15 and 20 weeks
2. Patient-Rated Tennis Elbow Evaluation (PRTEE) score measured using PRTEE questionnaire at baseline, 5, 10, 15 and 20 weeks
3. Elbow pain severity measured using a visual analog scale (VAS, 100, mm) at baseline, 5, 10 and 15 weeks
4. Pain-free grip strengths and maximum grip strength measured using a GRIP-D meter at baseline, 5, 10, 15 and 20 weeks
5. Echogenicity and vascularity measured by color Doppler sonography at screening or baseline, 10 and 20 weeks
6. Use of paracetamol as rescue medication measured using patient report at baseline, 5, 10, 15 and 20 weeks
7. Biomarkers of collagen metabolism measured using serum and urine samples at baseline, 10 and 20 weeks
8. Serum markers of inflammation measured using serum samples at baseline, 10 and 20 weeks

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Provision of written informed consent
2. Males, pre-menopausal females, peri- or post-menopausal females currently taking hormone replacement therapy between the ages of 18 and 70 years old
3. Females must use an approved form of birth control
4. Painful, chronic tendinopathy present in lateral elbow in one arm. The baseline elbow is > 40 on a scale of 100 mm (VAS: "0" representing no pain and "100" worst imaginable pain) during elbow extension and resisted wrist extension (Cozen's test)
5. The epicondylitis symptoms lasting at least 12 weeks or longer
6. A history of at least two periods of elbow pain lasting >10 days
7. BMI between 18.5 and 35 kg/m²
8. Participant must continue his/her normal physical activities during the study i.e. there should be no change in physical activity after the screening visit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
148

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. Radiological examinations show abnormalities such as arthritis and inflammatory arthropathy of the elbow joint in the target arm
7. Participants with a history of trauma, ligament damage, fracture, tumor or surgery of the elbow joint in the target arm
8. Proven and current symptomatic peripheral nerve entrapment syndrome
9. Proven and current symptomatic cervical facet arthrosis: C5-C6/C6-C7
10. Proven and current symptomatic radiculopathy
11. Fibromyalgia, chronic fatigue syndrome
12. New physical activity i.e. physical activity which was not present prior to the screening visit

13. Recent or current alcohol abuse
14. Participants with documented, active infection diseases such as HIV or hepatitis B/C
15. Clinically significant medical abnormalities which would make the subject unsuitable for the study, as judged by the investigator, such as mental disorders
16. Participant has documented renal failure, history of stroke, myocardial infarct or cancer
17. Concomitant and previous medication
17.1. Less than 6 months between the local treatment of epicondylitis with platelet-rich plasma (PRP), autologous conditioned plasma (ACP) or autologous whole blood (AWB) injections and inclusions in the study
17.2. Less than 3 months between the local treatment of epicondylitis with shockwaves or steroid injections and inclusion in the study
17.3. Less than 6 weeks between the local treatment of epicondylitis with botulinum toxin, glycosaminoglycan polysulfate (hyaluronic acid) or dextrose injections and inclusion in the study
17.4. Less than 15 days between the treatment and inclusion in the study: systemic or topical use of NSAIDs and analgesics, different from paracetamol; systemic opoids and corticosteroids; treatment for epicondylitis with acupuncture or physiotherapy
17.5. Less than 3 months between supplementation with food supplements containing horsetail extract, bamboo extract, silicic acid or silanol derivatives and inclusion in the study

Date of first enrolment
24/05/2018

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Belgium

Study participating centre
Ghent University Hospital
Department of Physical and Rehabilitation Medicine
Corneel Heymanslaan 10
Ghent
Belgium
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Study participating centre
Ghent University Hospital
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Study participating centre
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Stevenslei 20
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Study participating centre
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Sponsor information

Organisation
Bio Minerals NV

Funder(s)

Funder type
Industry

Funder Name
Bio Minerals NV

Results and Publications

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
Data sharing statement to be made available at a later date