

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/08/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
alexander.vantongel@ugent.be

Contact information

Type(s)
Public

Contact name
Mr Mattias Bonnarens

ORCID ID
<http://orcid.org/0000-0001-8177-1138>

Contact details
Zenderstraat 12
Destelbergen
Belgium
9070
+32 (0)9 3351327
mattias.bonnarens@biominerals.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design

Multi-center double-blind randomized placebo-controlled phase III 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

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 epicondylitis 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 measure

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

Secondary outcome measures

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

Overall study start date

28/03/2017

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

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 opioids 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
9000

Study participating centre

Ghent University Hospital

Department of Orthopaedic Surgery and Traumatology
Corneel Heymanslaan 10
Ghent
Belgium
9000

Study participating centre

AZ Monica

Department of Orthopaedic Surgery
Stevenslei 20
Deurne
Belgium
2100

Study participating centre

Ziekenhuis Oost-Limburg

Schiepse Bos 6
Genk
Belgium
3600

Study participating centre

AZ Sint-Lucas Gent

Department of Orthopaedic Surgery
Groenebriel 1
Ghent
Belgium
9000

Study participating centre

AZ Sint-Lucas Brugge

Department of Orthopaedic Surgery
Sint-Lucaslaan 29
Brugge
Belgium
8310

Study participating centre

AZ Sint-Lucas Brugge

Revalidatiecentrum
Sint-Lucaslaan 29
Brugge
Belgium
8310

Study participating centre

AZ Sint-Jan Brugge

Department of Orthopaedic Surgery
Ruddershove 10
Brugge
Belgium
8000

Study participating centre

UZ Antwerpen

Department Physical Medicine and Rehabilitation
Wilrijkstraat 10
Edegem-Antwerp
Belgium
2650

Study participating centre

Sportpraktijk De Merode

De Merodelei 197
Turnhout
Belgium
2300

Study participating centre

Sportartsenpraktijk
Michel Wittockstraat 21/001
Wilrijk
Belgium
2610

Sponsor information

Organisation
Bio Minerals NV

Sponsor details
Zenderstraat 12
Destelbergen
Belgium
9070
+32 (0) 9 228 20 00
ine.decock@biominerals.be

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Bio Minerals NV

Results and Publications

Publication and dissemination plan

1. Planned publication in a high-impact peer-reviewed journal.
2. Participants can contact the principal investigator to get access to their raw data and for discussion.
3. No additional files will be available.

Intention to publish date
31/12/2023

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