ISRCTN95838065 https://doi.org/10.1186/ISRCTN95838065

Evaluation of the effect of choline-stabilized orthosilicic acid (ch-OSA®) combined with magnesium in patients experiencing muscle cramps

Submission date
05/01/2026

Recruitment status
No longer recruiting

Registration date
06/01/2026

Overall study status
Completed

Last Edited
06/01/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Muscle cramps can be defined as sudden, involuntary and painful contractions of the skeletal muscles, lasting seconds to minutes and often accompanied by a palpable knotting of the muscle. Most cramps occur at rest and mainly at night and have a pronounced impact on the quality of sleep and life. Magnesium has been shown to have a poor efficacy for the treatment of muscle cramps. A recent case study demonstrated that the combination of choline-stabilized orthosilicic acid with magnesium decreased the number of weekly reported muscle cramps compared to magnesium only.
This study will investigate the effect of choline-stabilized orthosilicic acid combined with magnesium in patients experiencing muscle cramps.

Who can participate?
Adults between the ages of 18 and 75 years experiencing a minimum of two muscle cramp episodes per week.

What does the study involve?
Patients are randomly allocated to either receive choline-stabilized orthosilicic acid with magnesium or only magnesium (active control). All patients will be instructed to take two sachets daily for 6 weeks. Assessments will be done at the pre-screening visit, screening visit, inclusion to the study, and after 2, 4, and 6 weeks of treatment.

What are the possible benefits and risks of participating?
Choline-stabilized orthosilicic acid and magnesium may relieve muscle cramp symptoms. Considering the available information about choline-stabilized orthosilicic acid and magnesium, 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?
January 2022 to December 2023

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

Who is the main contact?
Prof. Dr Gaëtane Stassijns, Gaetane.Stassijns@uza.be

Contact information

Type(s)
Principal investigator

Contact name
Dr Gaëtane Stassijns

ORCID ID
https://orcid.org/0000-0002-9700-9065

Contact details
Drie Eikenstraat 655
Edegem
Belgium
2650
+32 (0)3 821 3983
Gaetane.Stassijns@uza.be

Type(s)
Public, Scientific

Contact name
Mr Mattias Bonnarens

ORCID ID
https://orcid.org/0000-0001-8177-1138

Contact details
Bio Minerals NV
Zenderstraat 12
Destelbergen
Belgium
9070
+32 (0)472 85 06 27
mattias.bonnarens@biominerals.be

Additional identifiers

Protocol serial number
20/1

Study information

Scientific Title
A randomized, double-blind, active-controlled study to assess the effect of CS-OSA-Mg on muscle cramps

Study objectives
The aim of the study is to compare the effect of oral intake of a proprietary mix of choline-stabilized orthosilicic acid and magnesium over a 6-week period on muscle cramps to oral intake of magnesium only.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/09/2021, Committee for Medical Ethics UZA-UA (Drie Eikenstraat 655, Edegem, 2650, Belgium; +32 (0)3 821 38 97; ethisch.comite@uza.be), ref: Project ID 20212021 - 0382 - Edge 1787 - BUN 3002021000124

Study design
Multi-center interventional double-blinded randomized active-controlled Phase III study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Skeletal muscle cramps

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

All participants will be instructed to take daily for 6 weeks, two sachets orally of either magnesium salts (1 sachet containing 200 mg magnesium in the form of magnesium gluconate, citrate, and malate), or the active ingredient (1 sachet containing 5 mg of silicon, 100 mg of choline in the form of choline-stabilized orthosilicic acid and 200 mg of magnesium in the form of magnesium gluconate, citrate, and malate). The trial starts with a pre-screening visit and a wash-out period during which the use of treatment for muscle cramps is not permitted.

Assessments will be done respectively at screening, at inclusion (baseline), and after 2, 4 and 6 weeks of treatment.

Intervention Type
Supplement

Primary outcome(s)

Number of cramp episodes per week measured using a daily digital cramp diary over 1 week without treatment and 6 weeks with treatment

Key secondary outcome(s))
1. Pain severity of cramp episodes measured using a daily digital cramp diary over 1 week without treatment and 6 weeks with treatment
2. Duration of cramp episodes measured using a daily digital cramp diary over 1 week without treatment and 6 weeks with treatment
3. Sleep disturbances because of cramps measured using a daily digital cramp diary over 1 week without treatment and 6 weeks with treatment
4. Number of days/nights without cramps measured using a daily digital cramp diary over 1 week without treatment and 6 weeks with treatment
5. Quality of life measured using the acute SF36v2 questionnaire at baseline and 6 weeks
6. Quality of sleep measured using the acute MOS-SS questionnaire at baseline and 6 weeks
7. Biomarkers of collagen metabolism measured using serum and urine samples at baseline and 6 weeks
8. Biomarkers of muscle damage measured using serum and urine samples at baseline and 6 weeks

Completion date
26/09/2024

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. Skeletal muscle cramps defined as: sudden, involuntary and painful contractions of the skeletal muscles, lasting seconds to minutes and often accompanied by a palpable knotting of the muscle.
5. Cramp frequency of at least 2 cramp days/nights per week in the previous month.
6. Cramp frequency of at least 2 days/nights suffering from cramps in the previous week (between the screening visit and baseline visit).
7. BMI between 18 and 35.
8. Subject must continue his/her normal physical activities during the study i.e. there should be no change in physical activity after the screening visit.
9. Subject has a smartphone/pc/tablet at home and is capable and willing to complete digital questionnaires daily.
10. History of magnesium use for cramp relief without a clear result on cramp symptoms.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
141

Key exclusion criteria
1. Subject 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 cooperate fully in the study.
4. Participating in another clinical trial in the last 90 days.
5. Pregnancy or breastfeeding.
6. BMI >35 or BMI <18 kg/m²
7. Recent or current alcohol abuse (consumption levels of more than 28 units per week) and drug abuse.
8. Subjects with documented, active infection diseases such as HIV, hepatitis B/C.
9. Clinically significant medical abnormalities which would make the subject unsuitable for the study, as judged by the investigator, such as mental disorders.
10. Subject with current active treatment for renal failure or cancer.
11. Subject with documented history of stroke or myocardial infarct.
12. Subject without a history of magnesium use for cramp relief.
13. Subject with a history of magnesium use for cramp relief with a clear result on cramp symptoms.
14. New physical activity i.e. physical activity which was not present prior to the screening visit.
15. Concomitant and previous medication:
15.1. Treatment with quinine sulfate: wash-out period of 1 week before the screening visit.
15.2. Supplementation with food supplements containing horsetail extract, bamboo extract, silicic acid or silanol derivatives: wash-out period of 3 months before the screening visit.
15.3. A change in the use of other therapies (except quinine sulfate) which may affect the number of cramps episodes (e.g. physiotherapy, calcium channel blockers, Vitamin E and B, diuretics, laxatives, beta-agonists, proton pump inhibitors, muscle relaxants) within 4 weeks before the screening visit or during the complete study period is not allowed.
Exception: Magnesium supplementation, if used stable for at least 4 weeks before the screening visit, should be continued up until the baseline visit (T0 visit). At the baseline visit (T0 visit) the Mg supplement will be replaced by the study dietary supplement (Mg or CS-OSA-Mg).

Date of first enrolment
17/01/2022

Date of final enrolment
16/08/2024

Locations

Countries of recruitment
Belgium

Czech Republic

Study participating centre
Antwerp University Hospital
Department of Physical Medicine and Rehabilitation
Drie Eikenstraat 655
Edegem
Belgium
2650

Study participating centre
OLV Aalst
Department of Physical Medicine and Rehabilitation
Moorselbaan 164
Aalst
Belgium
9300

Study participating centre
AZ Sint-Lucas Ghent
Pain center
Groenebriel 1
Ghent
Belgium
9000

Study participating centre
AZ Klina
Department of Physical Medicine and Rehabilitation
Augustijnslei 100
Brasschaat
Belgium
2930

Study participating centre

AZ Groeninge Kortrijk
Pain center
President Kennedylaan 4
Kortrijk
Belgium
8500

Study participating centre
Jan Yperman Hospital
Pain center
Briekestraat 12
Ieper
Belgium
8900

Study participating centre
Geert Leys Physiotherapist
Gistelse Steenweg 221
Bruges
Belgium
8200

Study participating centre
MediSterre General Practitioner
Oostmeetstraat 26
Koekelare
Belgium
8680

Study participating centre
Medisch Huis De Statie General Practitioner
Spoorwegstraat 114
Bruges
Belgium
8200

Study participating centre
Geertrui Neyt General Practitioner
Oudezakstraat 6b

Oedelem
Belgium
8730

Study participating centre
CCR Czech a.s.
Třída Míru 2800
Pardubice
Czech Republic
530 02

Study participating centre
CCR Brno
Hybešova 258/20
Brno
Czech Republic
602 00

Sponsor information

Organisation
Bio Minerals NV

Funder(s)

Funder type
Not defined

Funder Name
Bio Minerals NV

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date