

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	☐ Prospectively registered
		☐ Protocol
Registration date 06/01/2026	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 06/01/2026	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☒ 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

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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

Primary study design

Interventional

Study design

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

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

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Edegem

Belgium

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Study participating centre

OLV Aalst

Department of Physical Medicine and Rehabilitation

Moorselbaan 164

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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
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Study participating centre

Jan Yperman Hospital

Pain center
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Study participating centre

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Study participating centre

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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

