# A Randomized, Double-blind Placebocontrolled, Single-joint Study to Assess the Effect of Choline-Stabilized Orthosilicic Acid (ch-OSA) on symptoms of Knee Osteoarthritis

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
07/10/2015		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/10/2015	Completed	[X] Results		
<b>Last Edited</b> 10/12/2020	Condition category  Musculoskeletal Diseases	[] Individual participant data		

### Plain English summary of protocol

Background and study aims

Osteoarthritis (OA) is the most common type of arthritis and affects millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, causing stiffness, pain and a reduction in the range of movement. OA most often affects the knee joint, and is the leading cause of knee replacement surgery worldwide. Choline-Stabilized Orthosilicic Acid (ch-OSA) is a supplement containing a source of silicon. Silicon is vital for the formation of collagen in the body, which is an important component of bone and cartilage. Previous studies have shown that taking ch-OSA as a supplement could help to stimulate the production of bone collagen in women with weak bones (osteopenia), and so it could potentially be used as a treatment for other conditions which cause bone loss. The aim of this study is to find out whether taking ch-OSA supplements could help to relieve the symptoms of osteoarthritis.

### Who can participate?

Adults between 50 and 75 years old with osteoarthritis of the knee.

# What does the study involve?

Participants are randomly allocated into one of two groups. Those in the first group take two ch-OSA capsules a day for 12 weeks and those in the second group take a placebo (dummy pill) twice a day for 12 weeks. At the start of the study, and then again after 2, 6 and 12 weeks, participants in both groups are complete a questionnaire to find out if their symptoms have improved, as well as having a physical examination of their knees.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from?

1. Rheumatism Practice Genk (Belgium)

- 2. Institute of Rheumatology (Czech Republic)
- 3. National Institute of Rheumatic Diseases (Slovakia)

When is the study starting and how long is it expected to run for? March 2005 to July 2012

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

Who is the main contact? Mrs Nathalie Demeester

# Contact information

### Type(s)

Public

#### Contact name

Mrs Nathalie Demeester

#### Contact details

Zenderstraat 12 Destelbergen Belgium 9070

# Additional identifiers

Protocol serial number

05/1

# Study information

#### Scientific Title

A Randomized, Double-blind Placebo-controlled, Single-joint Study to Assess the Effect of Choline-Stabilized Orthosilicic Acid (ch-OSA) on symptoms of Knee Osteoarthritis

### **Study objectives**

The aim of the present study is to evaluate the effect of Choline-Stabilized Orthosilicic Acid (ch-OSA) on symptoms of knee osteoarthritis.

# Ethics approval required

Old ethics approval format

### Ethics approval(s)

- 1. Central Ethics Committee (University of Hasselt, Belgium), 02/03/2010, ref: B911520108293
- 2. National Institute of Rheumatic Diseases (Piestany, Slovakia), 08/03/2010
- 3. Institute of Rheumatology (Prague, Czech Republic), 30/03/2010, ref: 116/2010

# Study design

Multi-centre double-blind randomized placebo-controlled single-joint study

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Knee osteoarthritis

#### **Interventions**

Subjects are randomized in a placebo or a ch-OSA group using block randomisation. All subjects will be instructed to take daily for 12 weeks p.o. either placebo (2 capsules) or ch-OSA capsules (2 capsules: 2x 5 mg Si in the form of ch-OSA). The trial starts with a screening visit and a washout period during which the use of OA and pain medication is not permitted. The duration of the wash-out period is equal to the time of at least five drug half-lives of the OA and pain medication.

Evaluations will be done respectively at inclusion (baseline), and after 2, 6 and 12 weeks intake of ch-OSA or placebo: OA knee Pain Intensity (5-point Likert) of both knees, WOMAC, Subject Global Assessment, Physical examination of both knees, Fasting serum (safety, biomarkers), Fasting urine (safety, biomarkers).

### Intervention Type

Supplement

### Primary outcome(s)

The change in the WOMAC pain subscale from baseline to respectively week 2, 6, and 12 weeks of ch-OSA intake versus placebo.

# Key secondary outcome(s))

- 1. Subject Global Assessment of Response to Treatment measured using a visual analogue scale (VAS) at baseline, 2, 6 and 12 weeks
- 2. The change in the WOMAC physical function subscale at baseline, 2, 6 and 12 weeks
- 3. The change in the WOMAC stiffness subscale at baseline, 2, 6 and 12 weeks
- 4. The change in the WOMAC total index at baseline, 2, 6 and 12 weeks
- 5. The use of paracetamol as rescue medication at baseline, 2, 6 and 12 weeks
- 6. The change in biomarkers of collagen type II degradation (C-telopeptide fragments of type II collagen, CTX-II, urine), procollagen type II (N-terminal procollagen II, NPII, serum), and cartilage oligomeric matrix protein (COMP, serum) at baseline, 2, 6 and 12 weeks

# Completion date

20/07/2012

# Eligibility

# Key inclusion criteria

- 1. Aged between 50 and 75 years
- 2. Females must be either postmenopausal, surgically sterile or use an approved form of birth control.

- 3. OA of the knee as confirmed by radiography (weight-bearing, antero-posterior radiograph of the target knee: Kellgren and Lawrence grade II and III) during the screening visit or by a recent radiograph (< 6 months before baseline)
- 4. Primary (idiopathic) OA of one or both knees for at least 12 weeks prior to administration of study dietary supplement based on the American College of Rheumatology criteria. In addition to pain in the knee, at least 3 of the following 6 characteristics has to be present:
- 4.1. Over 50 years of age
- 4.2. Less than 30 minutes of morning stiffness
- 4.3. Crepitus on active motion
- 4.4. Bony tenderness
- 4.5. Bony enlargement
- 4.6. No palpable warmth of synovium
- 5. Symptomatic, target knee with OA pain intensity score on a 5-point Likert Scale of "moderate (2)" or "moderately severe (3)" after withdrawal of analgesic/anti-inflammatory medications. In the case that both knees have a pain score of "moderate (2)" or "moderately severe (3)", the knee with the highest pain score is chosen as the target knee.
- 6. Pain in target knee due to OA during load (e.g. standing, weight-bearing) or movement must exceed pain from other joints, or pain experienced due to other non-articular medical conditions 7. Subject must continue his/her normal physical activities during the study i.e. there should be not change in physical activity after the screening visit
- 8. WOMAC functional sub-scale score greater than 0

### Participant type(s)

Patient

### Healthy volunteers allowed

No

#### Age group

Other

#### Sex

All

#### Total final enrolment

166

#### 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 co-operate fully in the study
- 4. Participating in another clinical trial in the last 90 days
- 5. Pregnancy or breastfeeding
- 6. Morning stiffness > 30 minutes in duration
- 7. Subjects with a swollen or warm joint thought to be secondary to gout, pseudo gout or sepsis
- 8. Secondary OA of the target knee including Paget's disease of bone, articular fracture, major dysplasias or congenital abnormality, ochronosis, acromegaly, hemachromatosis, Wilson's disease and primary osteochondromatosis
- 9. Significant injury to the target joint within 6 months of trial start

- 10. Disease of spine or lower extremity joints of sufficient degree to affect assessment of the target joint
- 11. New physical activity i.e. physical activity which was not present prior to the screening visit
- 12. Recent or current alcohol abuse (consumption levels of more than 28 units per week) and drug abuse
- 13. Arthroplasty in the target knee and joint surgery of the target knee within 2 years prior to the start of the study
- 14. Subjects who have received chondrocyte transplants in any lower extremity joint
- 15. Subjects who belong in a high risk group for HIV
- 16. Clinically significant medical abnormalities which would make the subject unsuitable for the study as judged by the investigator
- 17. Subject has renal failure, documented history of stroke, myocardial infarct or cancer
- 18. Concomitant and previous medication:
- 18.1. Less than 28 days between the topical or systemic treatment with hyaluronic acid, glucosamine sulphate, glucosamine HCl, n-acetyl glucosamine and derivatives thereof such as chondroitin sulphate, glycosaminoglycans and the start of the study
- 18.2. Less than 3 months between the treatment with a slow acting drug for symptom relief and start of the study
- 18.3. Subjects who have used previous topical and/or systemic treatment with NSAID's or analgetica, different from paracetamol, such as ibuprofen, diclofenac, acetyl salicylic acid, piroxicam and indomethacin in a 14 days period prior to the start of the study
- 18.4. Subjects who have used medications with MMP-inhibitory properties (e.g. tetracyclines or structurally related compounds), or took oral (systemic, > 10 days duration) glucocorticoids in a 28 days period prior to start of the study
- 18.5. Subjects who have used compounds containing agents claiming to possess disease /structure modifying properties (e.g. diacerhein) in a 28 days period prior to start of the study 18.6. Subjects who received intra-articular injections in a the target knee of glucocorticoids within 3 months of the start of the study or any other injection (e.g. hyaluronic acid) within 6 months prior to the start of the study
- 18.7. 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 02/06/2010

Date of final enrolment 26/04/2012

# Locations

Countries of recruitment

Belgium

Czech Republic

Slovakia

### Rheumatism Practice Genk (Reumapraktijk Genk)

Bretheistraat 149 Genk Belgium 3600

# Study participating centre Institute of Rheumatology

Na Slupi 4 Prague Czech Republic 128 50

## Study participating centre National Institute of Rheumatic Diseases

Nabr. I Krasku 4 Piestany Slovakia 92123

# 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

# IPD sharing plan summary

Data sharing statement to be made available at a later date

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/01/2017	10/12/2020	Yes	No