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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

Submission date
07/10/2015

Recruitment status
No longer recruiting

Registration date
15/10/2015

Overall study status
Completed

Last Edited
10/12/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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9070

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/03/2005

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

Age group
Other

Sex
Both

Target number of participants
200 subjects

Total final enrolment

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

Study participating centre
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

Sponsor details
Zenderstraat 12
Destelbergen

Belgium
9070

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Bio Minerals NV

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date

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