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The “MEBAGA” study

Submission date
10/12/2014

Recruitment status
No longer recruiting

Registration date
04/02/2015

Overall study status
Completed

Last Edited
04/02/2015

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common disease affecting the joint. It can develop in any joint but it most often affects those that carry weight, such as the hips, spine and knees. It is caused by damage in and around the joint that can’t be fully repaired. Some of the cartilage (the protective layer covering the bones at the joint that ensures the joint moves smoothly) can become damaged or lost, leading to swelling (inflammation), pain and stiffness. Typical symptoms also include a deep, aching pain which can spread (radiate) from the affected joint, loss in the range of movement possible in the joint and the development of hard, bony, growths. Sufferers may also feel like their joints are crunching or grinding when they use them and find that they give way when weight is put on them. It is a long-term condition that can get worse over time. Treatment options include regular (sometimes prescribed) exercise, losing excess weight, drug treatments (such as painkillers and anti-inflammatories) and surgery. Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used to control OA symptoms. However, they are associated with a range of gastro-intestinal and cardiovascular side effects and other adverse effects on health. Due to safety concerns when taking these drugs, patients have turned to dietary supplements that claim to be beneficial in treating OA and safer than NSAIDS. This includes glucosamine sulfate (GS). Studies using GS to treat OA have suggested that this supplement can help protect joints against damage and repair damage that has been done. Glucosamine scored the highest level of evidence and strength of recommendation for knee OA symptoms in the current European League Against Rheumatism (EULAR) practice guidelines, and it is recommended by the latest Osteoarthritis Research Society International (OARSI) guidelines as a result. Other supplements that may help manage OA symptoms include methylsulfonylmethane (MSM) and boswellia acids (BA), both of which have been examined in previous studies. Here, we want to compare the benefits of taking MSM and BA with GS in mild to moderate knee OA.

Who can participate?
Adults aged between 25 and 85 years of age with OA of the knee.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (MB group) receive MSM and BA. Those in group 2 (GS group) are given GS supplements. All participants are asked to stop taking any anti-inflammatory drugs for at least 7 days before starting to take the supplements. They all undergo a clinical assessment and medical history at the time they start

the treatment and then at two follow up visits, one 2 months after the treatment begins and the other after 6 months. Any participants that experience pain are allowed to take paracetamol, pyroxicam or diclofenac. Participants are also asked to write down their anti-flammatory drug use in a diary for evaluation purposes.

What are the possible benefits and risks of participating?
Both supplements are safe. Adverse effects are gastric heaviness or diarrhea.

Where is the study run from?
1. General Hospital of Bari (Italy)
2. Policlinico di Bari (Italy)

When is the study starting and how long is it expected to run for?
February 2012 to December 2014

Who is funding the study?
Laborest Spa (Italy)

Who is the main contact?
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Protocol serial number
104/C.E. of 4th February 2013

Study information

Scientific Title
Comparative Effectiveness of Methylsulfonylmethane and Boswellic Acids versus Glucosamine Sulfate in the Treatment of Mild to Moderate Knee Arthritis

Acronym
MEBAGA

Study objectives
The aim of the present investigation is to better characterize the symptomatic activity of Methylsulfonylmethane (MSM) and Boswellic Acids (BA) in patients with OA of the knee, in comparison with the commonly prescribed Glucosamine Sulfate (GS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of General Hospital of Bari, Italy, 04/02/2013, ref. n.104/C.E.

Study design
Prospective, randomized controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
The required study population was patients affected by gonarthrosis

Interventions
Patients were randomized into two groups; the first taking the MSM and BA (MB group) and second the GS (GS group).

Intervention Type
Supplement

Primary outcome(s)
Response to treatment, defined as a decrease of pain on the VAS and an improvement in the patient’s global assessment score on the LEQUESNE INDEX from baseline at 2 and at 6 months.

Key secondary outcome(s))
Reduction in the patients' need to take anti-inflammatory drugs at 2 and 6 months. All analyses were performed at each FU, comparing results within each group and between the two groups.

Completion date
01/12/2014

Eligibility

Key inclusion criteria
1. Men and women >25 and <86 years of age
2. A diagnosis of OA of the knee according to the criteria of the American College of Rheumatology
3. Grade 3 Kellgren and Lawrence radiographic staging, in which the severity of the arthritis is assessed on a scale from 0-4, hypothesizing a sequential evolution from the manifestation of osteophytes through a reduction in the width of the joint space, to subchondral sclerosis and finally the formation of cysts
4. Frequent joint pain (several days a week) for at least 6 months before recruitment;
5. Pain in the knee, scored at least 2 cm on a 10 centimetric visual analogic scale (VAS), where 0 means no pain and 10 is the worst pain possible;
6. A score of >2 on the Lequesne pain-function index (LI). The LI is a disease-specific validated questionnaire that poses a series of questions about pain in the knee (five questions on a scale from 0 to 2, where 0 indicates no pain and 2 intense pain), functional limitation (four questions, using the same scale) and maximum walking distance (one question, with a score from 0 to 6, where 0 indicates the ability to walk for an unlimited distance and 6, the inability to cover 100 m). The maximum worst final score is 24.
Lack of symptoms in other joints was not taken into consideration.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Previous surgery of the affected knee
2. Disease processes such as rheumatoid arthritis, autoimmune diseases, systemic diseases, and tumors
3. Severe obesity (BMI >40 kg/m2)
4. Allergy to shellfish
5. Altered blood chemistry and kidney, liver, and metabolic (diabetes mellitus) function;
6. Intra-articular hyaluronic acid/cortisone infiltrations to the affected knee within 3 months before the start of the study

7. Systemic cortisone treatment taken within 3 months before the start of the study
8. Supplements (glucosamine, chondroitin sulfate, bromeline, etc) taken within 3 months before the start of the study (patients were also informed that they were not to be taken for the following 6 months).

Date of first enrolment
01/06/2013

Date of final enrolment
01/08/2014

Locations

Countries of recruitment
Italy

Study participating centre
General Hospital of Bari
Piazza g.cesare 11
Bari
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Study participating centre
Policlinico di Bari
Italy

Sponsor information

Organisation
Laborest Spa

Funder(s)

Funder type
Research organisation

Funder Name
Laborest Spa (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes