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A study to evaluate the potential effectiveness of a dietary supplement for osteoarthritis

Submission date
03/05/2017

Recruitment status
No longer recruiting

Registration date
19/05/2017

Overall study status
Completed

Last Edited
18/12/2017

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. The knee is the most common joint to be affected by OA and in many sufferers, the pain prevents people from moving around leading to muscle weakness and disability. Those with OA of the knee often require medication to help control the pain. However, there are now alternatives to the traditional medication such as herbal medications containing natural ingredients that may help with the pain and discomfort. UP1306 is an herbal formulation consists of herbs found naturally growing in northern China, Australia and other tropical, warm-temperature regions. The aim of this study is to determine the effects of an herbal formulation (UP1306) on discomfort and overall function when taken by individuals with OA of the knee over 12 weeks.

Who can participate?
Adults aged 35 to 75 years old who have symptoms of knee pain.

What does the study involve?
Participants are asked to attend seven study visits. The first visit determines participant's eligibility. At the second study visit, participants have their weight, height, blood and urine measured, have x-rays taken, take part in a six minute walk test and have a range of motion test. Participants are then randomly allocated participants to one of three groups. Those in the first group receive the herbal medication, those in the second group receive a placebo medication (a dummy) and those in the last group receive a similar medication to the herbal medication. Participants take the medication by mouth four times daily, two with their morning meal and two with their evening dinner. Participants are asked to keep a diary of their pain and discomfort levels. Participants attend five more follow up visits to assess their knee discomfort and function.

What are the possible benefits and risks of participating?
There are no direct benefits with participating. There are some risks involved with participating. Participants may feel discomfort when providing blood samples. There are risks of feeling faint, redness of the vein and bruising/bleeding at the needle puncture sight. There are risks of

radiation exposure due to having an x-ray. There are also risks with the study product causing allergic reactions such as rashes or itching, or causing more serious problems such as trouble breathing or swallowing.

Where is the study run from?
QPS-MRA (USA)

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

Who is funding the study?
Unigen (USA)

Who is the main contact?
Dr Douglas Kalman

Contact information

Type(s)
Scientific

Contact name
Dr Douglas Kalman

Contact details
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Additional identifiers

Protocol serial number
UNI-OA-2014

Study information

Scientific Title
The effects of Morus alba and Acacia catechu on quality of life and overall function in adults with osteoarthritis of the knee

Study objectives
Morus alba and Acacia catechu combined together will have a positive effect on quality of life in those adults with osteoarthritis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Asprire IRB, 02/14/2014, ref: Study ID UNI-OA-2014

Primary study design
Interventional

Study design
Prospective double-blind randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Healthy subjects with joint pain/discomfort, osteoarthritis

Interventions
Participants attend a baseline screening visit (visit one) that involves a medical history, medication review, urine test for pregnancy, anthropomorphic measures, and a physical examination. If participants are deemed as eligible, they are randomly allocated by a third party statistician to one of three treatments. The consulting statistician develops a randomization schedule and created a randomization log for use at the investigative site. The participants are allocated, in equal probability, to one of three product groups using a Block-6 randomization scheme. Each group of six consecutively-enrolled subjects are allocated among the three products with two participants to each product in random order. The three treatments are:

Group 1: A Morus alba and Acacia catechu based nutritional product UP1306
Group 2: Placebo
Group 3: Glucosamine + chondroitin

Participants attend six study visits, each visit lasts around two hours. The second study visit includes monitoring for changes in health and medication, questionnaires about discomfort, blood and urine tests, weight, blood pressure and heart rates measurements. Participants also have x-rays done. Participants are provided a breakfast of a bagel, cream cheese and orange juice. Participants are asked to perform a knee range of motion test, as well as a six minute walk test to see how far they can walk in six minutes. At this visit they are provided the study product and given instructions on how to use it. They are instructed to take four capsules of their assigned group's study product daily, two with a morning meal and two with an evening meal. They are required to fast after midnight prior to the study visits. They are asked to refrain from consuming alcohol or exercising for the 24 hours prior to the study visits. They are asked to complete a discomfort diary every day for the first seven days of taking the study product and after visit three they are required to complete the discomfort diary once a week for the remainder of the study.

The follow up visits (visits three, four, five, six and seven) includes monitoring for changes in health and medication, questionnaires about discomfort, blood and urine tests, weight, blood pressure and heart rates measurements. Participants are provided a breakfast of a bagel, cream cheese and orange juice. Participants are asked to perform a knee range of motion test. At visit five, six and seven they are asked to perform a six-minute walk test. At visit seven participants have a physical examination and provide blood and urine samples. The entire duration of the study is 12 weeks.

Intervention Type
Supplement

Primary outcome(s)
Effect of UP 1306 is measured using the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) pain sub-score at 12 weeks.

Key secondary outcome(s)
Acute effect of UP 1306 is measured using the Visual Analog Scale (VAS) discomfort ratings and the rescue medication use at 12 weeks.

Completion date
30/11/2014

Eligibility

Key inclusion criteria
1. Males and females, aged 35 to 75 years
2. BMI < 35 kg/m2
3. Knee pain for at least 15 of the 30 days prior to the start of the study
4. Symptoms of knee pain for at least 6 months
5. Grade I, II or III using Kellgren-Lawrence classification according to the screening X-ray
6. Able to walk
7. VAS-D score of ≥ 6 at the randomization visit. Subjects will have stopped taking his/her usual medication at the screening visit (which will be 7 to 28 days prior to the randomization visit) and will not have taken rescue medication for the 2 days prior to the randomization visit
8. For subjects with Type 2 Diabetes, has HgbA1c of ≤ 7.5%
9. Surgically sterile, post-menopausal or agrees to use an acceptable method of birth control
10. Agrees to not use any new vitamin and/or mineral supplement until after study completion
11. Agrees to not take any dietary or herbal supplements until after study completion. Seven-day washout period prior to visit 2 allowed
12. Agrees to not take any dietary or herbal supplements purported to decrease inflammation, body pain and/or improve joint health including glucosamine and MSM. Thirty-day washout period prior to visit 2 allowed
13. Willing and able to comply with the protocol including: attending 6 visits and discontinuing his/her usual OA medication and only taking acetaminophen in addition to the study product throughout the study period
14. Able to understand and sign the informed consent to participate in the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Active heart disease or presence of a pacemaker
2. Cerebrovascular disease
3. Uncontrolled high blood pressure (if deemed clinically significant by the investigator)
4. Renal or hepatic impairment/disease
5. Type I diabetes
6. Bipolar disorder
7. Parkinson's disease
8. Neuromuscular disease
9. Unstable thyroid disease
10. Immune disorder (such as HIV/AIDS)
11. Multiple sclerosis or any other autoimmune disorder
12. Any inflammatory arthritic condition
13. Acute septic arthritis
14. Fibromyalgia or other chronic pain syndromes (OA in locations other than knee allowed)
15. Gout, pseudogout and hyperuricemia
16. Paget's disease
17. Active peptic ulcer disease and/or history of upper gastrointestinal bleeding
18. Any medical condition deemed exclusionary by the Principal Investigator (PI)
19. A history of cancer (except localized skin cancer without metastases or in situ cervical cancer) within five years prior to screening
20. A history of psychiatric illness requiring hospitalization in the past 6 months
21. Ssignificant injury to the target joint within the past 12 months
22. History of joint replacement surgery at the index knee
23. History of arthroscopic surgery on the affected knee in the past 12 months or plans to have surgery in the next 6 months
24. Sulfa allergy or an allergy to sulphonamide
25. Allergy to shellfish and/or shrimp
26. Known allergy or sensitivity to any of the ingredients in the test product
27. Subjects with low blood pressure can only be included with PI approval due to potential worsening with Acacia catechu (Senegalia catechu).
28. Treated with oral corticosteroids within 4 weeks prior to screening
29. Intra-articular corticosteroids in the target joint within 3 months prior to screening
30. Hyaluronic acid injected in the target joint within 6 months prior to screening
31. Currently taking anticoagulants or antiplatelets
32. Unstable dose of medication (defined as fewer than 90 days at the same dose)
33. Currently taking any medication deemed exclusionary by PI
34. Evidence of hepatic or renal dysfunction as evidenced by ALT, AST, AP being > 2 times the upper limit of normal or serum creatinine value > 1.5 times the upper limit of normal or other clinically significant abnormal clinical laboratory value per PI discretion
35. History of drug or alcohol abuse in the past 12 months
36. Plans to have surgery over the next 12 weeks
37. Pregnant, lactating, or planning to become pregnant during the study period
38. Any condition or abnormality that, in the opinion of the investigator, would compromise the safety of the subject or the quality of the study data
39. Participating or has participated in another research study within 30 days prior to visit 2

Date of first enrolment

15/02/2014

Date of final enrolment

20/06/2014

Locations

Countries of recruitment
United States of America

Study participating centre
QPS-MRA
6141 Sunset Drive Suite 301
Florida
Miami
United States of America
33143

Sponsor information

Organisation
Unigen

Funder(s)

Funder type
Industry

Funder Name
Unigen

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

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