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Effect of a standardized hops extract on joint health

Submission date
15/10/2020

Recruitment status
No longer recruiting

Registration date
16/10/2020

Overall study status
Completed

Last Edited
19/10/2020

Condition category
Other

[ ] 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 degenerative joint disease and a frequent cause of physical disability among older adults. OA affects the hands, lower back, neck and weight-bearing joints such as the knees, hips, and foot joints. Symptoms of OA range from stiffness and intermittent mild pain to severe joint pain. Humulus lupulus L. (hops) is widely used as a bittering agent in beer brewing and has a long-standing tradition of medicinal use in Europe. Despite the popularity of hops, controlled clinical studies on the effectiveness of hops in joint health are currently lacking. The aim of this study is to assess the effectiveness and safety of a standardized hops extract to test if a nutritional supplement can improve joint health.

Who can participate?
Adults with osteoarthritis of the knee who are 40 to 75 years of age.

What does the study involve?
Participants are randomly allocated to one of three groups: placebo (dummy supplement) or a low or high dose of hops extract. Participants will be required to make a total of two study visits (day 1 and day 15). On day 1, participants will walk on a flat surface for 20 meters and their joint health will be assessed with questionnaires. Participants will consume the supplement for the following 14 days and record their joint health daily. On day 15, participants will walk on a flat surface for 20 meters again and their joint health will be assessed with questionnaires.

What are the possible benefits and risks of participating?
Participants receiving the hops extract are expected to see an improvement in their joint health. There will be no immediate direct benefit to those taking the placebo. Risks of the blood sampling procedure include bruising, hematoma, dizziness, fainting, pain upon needle stick, and the remote risk of infection. These risks will be minimized by having trained personnel obtain blood samples using standard procedures. Risks will be further minimized by screening if participants have any issues that they know of in giving blood.

Where is the study run from?
Research Testing Labs (USA)

When is the study starting and how long is it expected to run for?
May 2006 to October 2006

Who is funding the study?
Pharmachem Laboratories, Inc. (USA)

Who is the main contact?
1. Gregory Bonfilio
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2. Dr. Ralf Jäger
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RTL # 333.0406

Study information

Scientific Title
Effects of standardized hops (Humulus lupulus L.) extract on joint health: a randomized, placebo-controlled, double-blind, multiple-dose study

Study objectives
Humulus lupulus L. (hop) is widely used as a bittering agent in beer brewing and has a long-standing tradition of medicinal use in Europe. Despite the popularity of hops, controlled clinical studies on the efficacy of hops in joint health are currently lacking. The aim of this study is to evaluate the efficacy and safety of 14-days oral supplementation of a standardized hops extract, containing 30% alpha acids, on individuals with osteoarthritis of the knee.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2006, Institutional Review Board of RTL, Inc. (127 Old Cutter Mill Road, Great Neck, NY 11021, USA; +1(0) 516 773 7788; email not provided), ref: not provided

Study design
Single-center interventional randomized placebo-controlled double-blind multiple-dose study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Improvement of joint health in individuals with osteoarthritis of the knee

Interventions
Participants will be assigned to ingest in a random order either 1 g or 2 g per day of a standardized hops extract (supercritical carbon dioxide hops extract containing 30% alpha acids (Perluxan™, Pharmachem Laboratories, Inc., 265 Harrison Avenue, Kearny, NJ 07032, USA)) or placebo for 14 days.

Intervention Type
Supplement

Primary outcome measure
Perceived pain measured using WOMAC 5-item Symptom Assessment at hours 1, 2 and 4 post-dosing on day 1, daily on days 2 through 14 (for question 1, walking on a flat surface); daily on days 2 through 14 for questions 2-5 (going up and down stairs, at night while in bed, sitting or lying, standing upright).

Secondary outcome measures

1. Time to perform a 20-meter walk on a flat surface measured at baseline (day 1) and day 15
2. Consumption of rescue medication measured using self-recorded dairies daily for 14 days
3. Adverse events measured using self-recorded dairies daily for 14 days
4. Safety markers (Na, K, Ca, Cl, CO2, anion gap, glucose, blood urea nitrogen (BUN), creatinine, T Protein, albumin, T bilirubin, AST, ALT and ALK phosphatase) measured using fasting blood and urine samples at baseline (day 1) and day 15

Overall study start date
01/01/2006

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. Prospective subject is a male or female who is 40 to 75 years of age
2. Prospective subject has unilateral or bilateral OA of the knee (according to the ACR Criteria, Class I, II or III) without overt clinical signs of inflammation (i.e. joint swelling, effusion, erythema, palpable increased warmth)
3. Prospective subject has had pain in the target knee for at least six months prior to the study start
4. Prospective subject is able to walk unassisted (the use of a walking stick, crutch, and/or knee brace is permitted, at the discretion of the investigator)
5. Prospective subject has a score of greater or equal of 30, and less or equal of 80 at visit 1 on the first item of the WOMAC pain subscale (pain walking on a flat surface)
6. Prospective subject must be willing and able to carry out the provisions of the study, complete self-assessments and diaries, and read, sign and date an informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
36

Total final enrolment
36

Key exclusion criteria
1. Female prospective subject is pregnant, lactating (or lactating less than 6 weeks prior to the start of the study), less than three months postpartum, or wishes to become pregnant during the study. Female subject, capable of conceiving a child, is not willing to use, if necessary, an acceptable form of contraception, according to the principal investigator, for the duration of the study

2. Prospective subject has been diagnosed as having any inflammatory arthritis, or has any acute joint trauma at the knee with OA.
3. Prospective subject has signs of active target joint inflammation including redness, warmth, and/or a large, bulging effusion of the target knee joint with the loss of normal contour of the joint at the baseline examination (visit 1).
4. Prospective subject has secondary OA of the study target joint including septic arthritis, inflammatory joint disease, or other concurrent arthritic disease, rheumatoid arthritis, gout, Paget's disease of bone, articular fracture, major dysplasias or congenital abnormality, ochronosis, acromegaly, hemochromatosis, WIlson's disease, primary osteochrondromatosis, fibromyalgia, spinal disorders, and/or musculoskeletal disease.
5. Prospective subject has morning stiffness of greater than 30 minutes duration.
6. Prospective subject has had knee replacement surgery of the target joint.
7. Prospective subject has an active malignancy of any type or history of malignancy (e.g. breast cancer). (Subjects who have a history of basal cell carcinoma that has been treated are acceptable. Subjects with a history of other malignancies that have been surgically removed, and who have no evidence of recurrence for at least 5 years before study enrollment are also acceptable).
8. Prospective subject has clinically significant abnormal screening laboratory test values, at the discretion of the principal investigator.
9. Prospective subject has a history of cardiac event (e.g. myocardial infarction).
10. Prospective subject has coronary artery disease or suffers other clinical manifestations of atherosclerotic disease (e.g., peripheral arterial disease, abdominal aortic aneurysm, symptomatic carotid artery disease such as ischemic stroke).
11. Prospective subject has undergone coronary artery bypass graft (CABG) surgery.
12. Prospective subject has current asthma.
13. Prospective subject has an allergy to ibuprofen, aspirin, acetaminophen, or any NSAID medications.
14. Prospective subject has a chronic pain syndrome in the judgment of the principal investigator and has shown minimal response to any analgesic or anti0inflammatory medication.
15. Prospective subject is receiving therapy for chronic pain conditions for indications other than OA.
16. Prospective subject has class IV unilateral or bilateral OA of the knee, according to the ACR Criteria.
17. Prospective subject has had surgery (including arthroscopy) and/or significant injury of the target knee, within six months prior to study enrollment, or has an anticipated need for any surgical or other invasive procedure (e.g., arthroscopy, lavage, or general surgery) that will be performed during the course of the study, or within the 2 weeks after the completion of the study.
18. Prospective subject uses assistant devices other than a walking stick, crutch, and/or knee brace.
19. Prospective subject has had physical therapy or acupuncture for the target joint during the four weeks prior to the study enrollment, or intends to engage in such activities during the study period.
20. Prospective subject is taking glucosamine, with or without chondroitin sulfate, MSM, and/or shark cartilage, who has not been stabilized on therapy within the three-month prior to the screening evaluation, or who does not expect to remain on the same or comparable medication and corresponding dose.
21. Prospective subject is taking Sam-e.
22. Prospective subject has received any analgesic or anti-inflammatory drug(s) within five drug half-lives prior to dispensing study materials.
23. Prospective subject is taking hypolipidemic agents and has not been stabilized on therapy within the three-month period prior to the screening evaluation, or does not expect to remain

on the same or comparable medication and corresponding dose.
24. Prospective subject takes or intends to take during the study blood pressure medications called ACE inhibitors, furosemide, fluconazole or ketoconazole, phenytoin, warfarin, or aspirin (except prophylactic aspirin at less than 81 mg daily, if stable for 3 months).
25. Prospective subject take H2-antagonists and/or proton pump inhibitors.
26. Prospective subject take any medication which inhibits platelet aggregation and/or anticoagulant drugs.
27. Prospective subject take antidepressants, unless stable 3 months prior to enrollment.
28. Prospective subject has a history or the current presence of stomach (peptic) ulcer disease or stomach bleeding.
29. Prospective subject has a significant history or the current presence of uncontrolled metabolic disorders, thyroid disease, diabetes mellitus type I or II, renal disease, hepatic disease, and/or untreated hypertension (defined as systolic blood pressure of greater than 160, and/or diastolic blood pressure of greater than 100).
30. Prospective subject has any chronic disease which limits his/her activities.
31. Prospective subject has a history or the current presence of significant haematological disorders.
32. Prospective subject has received/had intra-articular, oral and/or parenteral corticosteroids, within the 2 months prior to study enrollment or plans to receive such therapies during the study period.
33. Prospective subject has received hyaluronic acid injections in the target joint, within 6 months of randomization.
34. Prospective subject has a body mass index (BMI) of greater than 39.9.
35. Prospective subject has a known allergy or sensitivity to any of the test product's ingredients.
36. Prospective subject has a history of alcohol and/or other drug abuse, within the past year.
37. Prospective subject is unwilling to maintain his/her smoking behavior for the duration of the study (e.g., if the subject doesn't smoke, will not start, if the subject does smoke, will not change amount or frequency).
38. Prospective subject has participated in any investigational study within the previous 30 days (or is currently participating in any).
39. Prospective subject has any findings on physical examination, in results of laboratory analyses and/or any medical conditions or concomitant medications or supplements which, in the opinion of the investigator, may place the individual at risk and/or confound the results of the study.

Date of first enrolment
19/05/2006

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
United States of America

Study participating centre
Research Testing Laboratories, Inc.
127 Old Cutter Mill Road

Great Neck, NY
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Sponsor information

Organisation
Pharmachem Laboratories, Inc.

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Pharmachem Laboratories, Inc.

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/04/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ralf Jäger (ralf.jaeger@increnovo.com).

IPD sharing plan summary

Available on request