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A randomised, double-blind, placebo-controlled, dose-ranging two-centre study to evaluate the efficacy and safety of Devil's Claw in the treatment of knee and hip osteoarthritis

Submission date
13/11/2006

Recruitment status
Stopped

Registration date
13/12/2006

Overall study status
Stopped

Last Edited
05/08/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00295490

Protocol serial number

Version 20

Study information

Scientific Title
A randomised, double-blind, placebo-controlled, dose-ranging two-centre study to evaluate the efficacy and safety of Devil's Claw in the treatment of knee and hip osteoarthritis

Study objectives
1. Devil's Claw has anti-inflammatory properties (as assessed by the reduction in pain, stiffness and disability aspects on the Western Ontario and McMaster Universities Arthritis Index [WOMAC]) in chronic osteoarthritis (OA) of the knee and/or hip after 16 weeks of treatment, as compared to placebo.
2. A dose response effect exists in the treatment of osteoarthritis of the knee/hip by Devil's Claw.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire, Local Research Ethics Committees, approval: 14/04 /2004, ref: LREC 049/04/t

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled dose-ranging two-centre study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of knee and/or hip

Interventions
Patients randomised to one of four groups:
1. Placebo medication
2. Devil's Claw (240 mg/d extract, equivalent dose of 2.4 - 4.8 mg/d)
3. Devil's Claw (960 mg/d extract, equivalent dose of 9.6 - 19.2 mg/d)
4. Devil's Claw (1920 mg/d extract, equivalent dose of 19.2 - 40.4 mg/d)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Devil's Claw (Harpagophytum procumbens)

Primary outcome(s)
Reduction in WOMAC total score from baseline to week 16.

Key secondary outcome(s)
1. Secondary efficacy analysis
2. Change in WOMAC subscales (pain, stiffness, disability) from baseline to end of treatment at week 16
3. Quality of Life assessments (Short Form health survey [SF-36])
4. Changes in the subject's well-being
5. Changes in subject's overall global assessment
6. Changes in attitudes and health beliefs to Complementary/Alternative Medicine (CAM)
7. Group differences between adverse event reporting

Completion date
30/09/2008

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Patients with either a pragmatic diagnosis of:
1.1. Osteoarthritis of the knee, with no other known rheumatological condition and who report the following clinical features (based on the American College of Rheumatology [ACR] classification for knee OA1):
1.1.1. Knee pain on most days of the previous month
1.1.2. Morning stiffness of less than 30 minutes duration
1.1.3. "Stiffness" in resting the joint, and
1.1.4. Aged over 40 years
1.2. Osteoarthritis of the hip, with no other known rheumatological condition and who report the following clinical features (based on the ACR classification for hip OA2) - hip pain on most days of the previous month and at least two of the following three features:
1.2.1. Erythrocyte sedimentation rate (ESR) less than 20 mm/hour
1.2.2. Radiographic femoral or acetabular osteophytes
1.2.3. Radiographic joint space narrowing (superior, axial and/or medial), and
1.2.4. Aged over 45 years of age
The diagnosis of osteoarthritis will be confirmed by X-ray.
2. Only patients who have grade 2 to 4 of the Kellgren and Lawrence scale will be recruited (The Kellgren and Lawrence scale ranges from grade zero to grade four where grades zero and one represent doubtful osteoarthritic changes and therefore a doubtful diagnosis)
3. Patients who have been on stable medication (conventional or complementary, including nutritional medicine) for the past three months, but are still getting symptoms (incomplete responders)
4. Only those patients who record baseline pain scores on the WOMAC scale of at least 20 mm on the Visual Analogue Scale (VAS) for a minimum of six out of seven days monitored during the period from Clinic Visit one (screening) and Clinic Visit two (baseline)
5. Ability to comply with the requirements of the study and to give informed consent
6. For women of child-bearing potential: negative pregnancy test

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participation in an investigational trial within 30 days prior to enrolment
2. Previous treatment with Devil's Claw within 90 days prior to enrolment
3. Patients awaiting a replacement knee or hip joint
4. Patients with other conditions that cause pain
5. Patients with congenital dislocation of the hip
6. Patients who have had operations on their hip due to previous trauma
7. Patients with severe co-morbidities - including severe cardiac or pulmonary disease and cancer
8. Dementia, psychoses, or other significant impairment of mental status that would prohibit sufficient comprehension, provision of informed consent and to allow undertaking of the necessary self-care or toxicity reporting
9. Patients taking corticosteroid medication
10. Known allergies against any of the ingredients of the treatments
11. Patients who would be unable to complete the self assessment forms, or to attend for X-ray and clinical examination
12. Patients with other known rheumatic disease such as rheumatoid arthritis
13. Patients with the diagnosis gout
14. Patients who report a red or hot swollen joint (which is unlikely to be due to OA), and would require further rheumatological assessment
15. Patients with conditions known to be contraindicated to the study medication i.e. patients with gastric or duodenal ulcers; gallstones; patients taking drugs for arrhythmias; patients with heart failure
16. Patients who are pregnant, trying to become pregnant or breastfeeding

Date of first enrolment
12/12/2004

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Research organisation

Funder Name
Southampton Complementary Medicine Research Trust (UK)

Funder Name
University of Southampton (UK)

Alternative Name(s)
University of Southampton UK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Pascoe Pharmazeutische Praparate GmbH (Germany)

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?
Basic results		09/09/2011		No	No