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The effectiveness of harpagophytum procumbens cream in the relief of osteoarthritic pain of the knee

Submission date
29/01/2016

Registration date
09/02/2016

Last Edited
09/02/2016

Recruitment status
No longer recruiting

Overall study status
Completed

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
Harpagophytum Procumbens (commonly known as devil's claw) is a plant that originates from southern Africa. It's roots are used to reduce pain and fever. The chemicals thought to be responsible for the plants pain killing properties are Harpagoside, Harpagide and Procumbide. This study is testing the pain relieving properties of a cream containing Harpagophytum Procumbens in people suffering from knee pain caused by osteoarthritis.

Who can participate?
Adults suffering from osteoarthritis of the knee.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given a harpagophytum containing cream to apply to their knee. Those in group 2 are given a placebo cream that looks and feels like the harpagophytum containing cream to apply to their knee. All participants assess for themselves the amount of pain they are feeling before and after they have put on the cream.

What are the possible benefits and risks of participating?
There are no risks to participating in this study as the ingredients of the cream are absolutely free of any possible adverse effects.

Where is the study run from?
A number of orthopedic private practices in Thessaloniki and Volos (Greece)

When is the study starting and how long is it expected to run for?
February 2016 to August 2016

Who is funding the study?
Synapse Hellenic Pharmaceuticals & Services

Who is the main contact?
Dr Eleftherios Teperikidis

Contact information

Type(s)
Scientific

Contact name
Dr Eleftherios Teperikidis

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of harpagophytum procumbens cream in the relief of osteoarthritic pain of the knee: a double blind, placebo controlled, randomised interventional study

Acronym
HARPAIN TRIAL

Study objectives
The hypothesis of the study is that harpagophytum Procumbens cream is better than placebo in the relief of osteoarthritic knee pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double blind, placebo controlled, randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
Patients who meet the radiographic inclusion criteria will be asked to initially evaluate the level of their pain in the knee on a Visual Analogue Scale (0 – 10). Based on the V.A.S scale result and the level of osteoarthritis it is decided by the researcher whether the inclusion criteria are met. All patients will be asked to sign a patient release form before participating in the trial. Patients will then be randomly assigned to either treatment or placebo group.

In the treatment group, 3 mL of a harpagophytum containing cream will be applied on the affected knee. The placebo group will receive 3 mL of a cream that has been designed to have the same color, smell and texture as the active cream.

Ten minutes after the application of the cream, patients will be asked to evaluate the level of the pain that they feel on a Visual Analogue Scale (0 – 10), as well as if they experience any adverse effect (skin reaction etc.). Through the ten minute waiting period, the researcher will complete the The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), an established and accredited questionnaire used in high quality clinical trials, evaluating the problems caused by Osteoarthritis in patient's every day life.

At the end of the study all researchers will fill out a questionnaire regarding the execution of the trial as per the instructions given.

Intervention Type
Drug

Drug/device/biological/vaccine name(s)
Harpagophytum procumbens

Primary outcome measure
Patient improvement on pain as evaluated by a Visual Analogue Scale (0-10) ten minutes after application of the cream.

Secondary outcome measures

N/A

Overall study start date
01/02/2016

Completion date
01/08/2016

Eligibility

Key inclusion criteria
1. Osteoarthritis Stage (Kellgren & Lawrence Scale) 2 - 3
2. Patient’s Knee - Pain Self Evaluation (VAS 0 - 10) 4, 5, 6, 7

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Osteoarthritis Stage (Kellgren & Lawrence Scale) 0, 1, 4
2. Patient’s Knee- Pain Self Evaluation (VAS 0 - 10) 0 – 3 , 8 - 10
3. Use of analgesic or anti-inflammatory medications, topical or oral on the day of the study

Date of first enrolment
01/02/2016

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
Greece

Study participating centre
Number of orthopedic private practices
Thessaloniki and Volos
Greece
54635

Sponsor information

Organisation
Synapse Hellenic Pharmaceuticals & Services

Sponsor details
Egnatias 117
Thessaloniki
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Sponsor type
Industry

ROR
https://ror.org/01vx59p26

Funder(s)

Funder type
Industry

Funder Name
Synapse Hellenic Pharmaceuticals & Services

Results and Publications

Publication and dissemination plan

Intention to publish date
01/08/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request