

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

Submission date 29/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/02/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/02/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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Additional identifiers

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

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s)

N/A

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

<https://ror.org/01vx59p26>

Funder(s)

Funder type

Industry

Funder Name

Synapse Hellenic Pharmaceuticals & Services

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request