Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study the effect of topical application of 1% Stachys lavandulifolia extract gel and Declofenac gel in knee osteoarthritis on the pain and functional disability in patients with primary monoarticular knee osteoarthritis

Protocol summary

Study aim

The effect of topical gel application of 1% Stachys lavandulifolia and Diclofenac gel in Knee Osteoarthritis on the rate of pain and functional disability in patients with knee osteoarthritis

Design

This double blinded clinical trial was conducted by 150 patients with primary knee osteoarthritis who were randomly divided into 3 groups of 50 persons including control group receiving placebo, group receiving 1% Stachys lavandulifolia gel and group receiving 1% diclofenac gel.

Settings and conduct

This double blinded clinical trial study was conducted on the patients referred to hospitals in Shahrekord University of Medical Sciences. Participants information held secretly and other participants had not access to these information.

Participants/Inclusion and exclusion criteria

A definite diagnosis of primary osteoarthritis in a knee based on the doctor's diagnostic criteria is inclusion criteria. Primary osteoarthritis in both patient's knees is exclusion criteria.

Intervention groups

Intervention group: 1-Topical Gel Aqueous Hydrochloric Acid Extract with 200mg of Celecoxib Capsule 2- A topical gel with a percentage of diclofenac with 200 mg of celecoxib capsules. Control group: Topical Gel Placebo with 200 mg Celcioxide Capsules

Main outcome variables

The present study demonstrates that it can be used Stachys lavandulifolia gel can be used to reduce the pain in patients with primary knee osteoarthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190125042486N1**
Registration date: **2019-02-22, 1397/12/03**
Registration timing: **retrospective**

Last update: **2019-02-22, 1397/12/03**
Update count: **0**

Registration date

2019-02-22, 1397/12/03

Registrant information

Name

Abolghasem sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 0061

Email address

gh_sh_fr51@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date

2018-03-30, 1397/01/10

Actual recruitment end date

2019-01-10, 1397/10/20

Trial completion date

2019-01-10, 1397/10/20

Scientific title
Study the effect of topical application of 1% Stachys lavandulifolia extract gel and Declofenac gel in knee osteoarthritis on the pain and functional disability in patients with primary monoarticular knee osteoarthritis

Public title
Study the Effect of Topical Application of 1% Stachys lavandulifolia Extract Gel vs Diclofenac Gel in Knee Osteoarthritis on the pain and functional disability in patients with primary monoarticular knee osteoarthritis

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
A definite diagnosis of primary osteoarthritis in a knee based on the doctor's diagnostic criteria the existence of pain at least for two weeks before beginning treatment the age range between 45 years to 75 years old

Exclusion criteria:
Primary osteoarthritis in both patient's knees Acute disease in liver or kidney Ulcer pepticemia Diabetes Thyroid or parathyroid disease Rheumatic arthritis coagulation disease or consumption of anticoagulant drugs History of ischemic stroke or hemorrhage History of deep vein thrombosis History of intra-articular injection during the last 6 weeks Sensitivity to each form of anti-inflammatory drugs Acute and pregnancy trauma History of alcohol use and drug abuse Skin diseases, infection or ulcers in the location of tropical use of medication Oral use of other anti-inflammatory drugs and other effective compounds in the treatment of osteoarthritis 10 days before the beginning of the study History of fracture or knee surgery

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **150**
Actual sample size reached: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization (using random numbers table and software), samples devoted to each of the three groups: A, B and C, each group consisting of 50 sample.

Blinding (investigator's opinion)
Double blinded

Blinding description
All information of participants were recorded confidentially and secretly without name and with the code, and participants had not inform about the other participants other, clinical care provider also had not aware of the primary pain rate of participants

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences

Street address
Deputy for Research and Technology, Kashani Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8814646885

Approval date
2018-03-04, 1396/12/13

Ethics committee reference number
IR.SKUMS.REC.1397.66

Health conditions studied

1

Description of health condition studied
primary monoarticular knee osteoarthritis

ICD-10 code
M19.9

ICD-10 code description
Osteoarthritis, unspecified site

Primary outcomes

1

Description
pain and functional disability

Timepoint
Six weeks

Method of measurement
Data were collected by interview, Western Ontario and McMaster Universities Arthritis Index Standard Questionnaire (WOMAC), and Vase Analog scale(VAS).

Secondary outcomes

1

Description

Patient's function status

Timepoint

4 times and days 0, 14,28, 42

Method of measurement

intensity of pain by Visual Analog Scale (VAS) scale and the rate of pain on the patient,s function by Western Ontario and McMaster Universities Arthritis Index(WOMAC) questionnaire were measured

Intervention groups

1

Description

Intervention group: Topical Gel Aqueous Hydrochloric Acid Extract with 200 mg of Celecoxib Capsule

Category

Diagnosis

2

Description

Control group: Topical Gel Placebo with 200 mg Celcioxide Capsules

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational Clinic in Shahrekord University of Medical Sciences

Full name of responsible person

Morteza Dehghan

Street address

Parastar

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814646885

Phone

+98 38 3333 0061

Email

dehghan_m@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Kamal Solati

Street address

Deputy for Research and Technology, Shahrekord University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814646885

Phone

+98 38 3333 0061

Email

solat-k@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

No

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Hsmidreza Asadian

Position

Rezident

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Deputy for Research and Technology, Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814646885

Phone

+98 38 3333 0061

Email

m_asadian67@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Hamidreza Asadian

Position
Rezident

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

Street address
Deputy for Research and Technology,Kashani Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8814646885

Phone
+98 38 3333 0061

Email
m_asadian67@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Abolghasem Sharifi

Position
Master of science

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Deputy for Research and Technology

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8814646885

Phone
+98 38 3333 0061

Email
gh_sh_fr51@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no any decision to share data

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available