

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study the effect of topical application of 1% Stachys lavandulifolia extract gel and Diclofenac 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 Diclofenac 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 topical 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