Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of effectiveness of topical basil oil with Diclofenac gel in patients with knee osteoarthritis

Protocol summary

Summary

This is a single-Blinded (at the level of researchers and bio-statisticians) randomized clinical study to compare the effects of basil oil with Diclofenac gel on patients with clinical symptoms of knee osteoarthritis. 90 patients after taking signed informed consent according to American college of rheumatology classification criteria are accepted.The main exclusion criteria included: sensitivity to basil oil or Diclofenac gel or celecoxib; unwillingness to continue to participate in the study; joint replacement; concomitant use of glucosamine and chondroitin sulfate; knee corticosteroid or hyaluronic acid injection in the past 3 months; other articular corticosteroid or hyaluronic acid injection in the past 1 month; pregnancy or Lactating women; using oral or topical corticosteroid 14 days ago befor study be started. the patient will allocate to two arms using block randomization. Celexib tab 100 milligrams also given to the patients to use for pain relief if needed. Drugs will be encoding and without the name, three times a day for 2 weeks will prescribe to intervention groups. Patients at the beginning and once every 2 week from the beginning of the study will be evaluated for General status of pain, physical function and stiffness of joint by the WOMAC questionnaire until the fourth week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081711341N7**
Registration date: **2017-09-12, 1396/06/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-12, 1396/06/21

Registrant information

Name
Mohammad Hashem Hashempur
Name of organization / entity
Fasa University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1233 8476
Email address
hashempurm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Fasa University Of Medical Sciences

Expected recruitment start date

2017-09-15, 1396/06/24

Expected recruitment end date

2017-10-31, 1396/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of topical basil oil with Diclofenac gel in patients with knee osteoarthritis

Public title

The evaluation of effectiveness of topical basil oil on clinical symptoms in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the age between 30-70 years old; patient's written informed consent for inclusion; diagnosis of osteoarthritis by the orthopedist according to American College of Rheumatology classification

criteria; grade I to III osteoarthritis according to Kellegren-Lawrence system of classification; pain of at least one knee during 3 months ago; no congenital abnormality of lower extremity. Exclusion Criteria: hypersensitivity to basil oil or Diclofenac gel or celecoxib; unwillingness to continue to participate in the study; secondary osteoarthritis due to rheumatologic diseases like rheumatoid arthritis, gout, pseudo gout, infected arthritis, metabolic arthritis, traumatic arthritis; joint replacement; concomitant use of glucosamine and chondroitin sulfate; knee injection of corticosteroid or hyaluronic acid in the past 3 months; other articular corticosteroid or hyaluronic acid injection in the past 1 month; use of oral or topical analgesic drugs 3 days before enrollment; pregnancy or Lactating women; alcohol addiction; drug abuse; using oral or topical corticosteroid 14 days days before enrollment; skin lesions of knee; disability to cooperate in filling the forms (cognitive or language disorder); the patient who use drugs that interact with celexib (e.g. lithium, fluconazole, warfarin, diuretics, ACE inhibitors like captopril, ARBs like losartan); patient with IBD or PUD; obesity (BMI ≥ 35 kg/m^2); use of physical modalities 2 weeks before enrollment (such as physical treatment, Acupuncture and Transcutaneous Electrical Nerve Stimulator).

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Fasa University of Medical Sciences, Ebnesina square, Fasa

City
Fasa

Postal code

Approval date
2016-03-08, 1394/12/18

Ethics committee reference number
IR.FUMS.REC.1394.39

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M17

ICD-10 code description
Gonarthrosis

Primary outcomes

1

Description
General status of pain, physical function and stiffness of patients

Timepoint
At the beginning of intervention and after 2 week, 4 weeks after the beginning of intervention

Method of measurement
WOMAC questionnaire

Secondary outcomes

1

Description
Knee flexion angle

Timepoint
At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement
by using of standard goniometer

2

Description
Speed of walking

Timepoint
At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement
with measuring time of 8 meters walking

3

Description
The need for celexib 100 milligrams tablets

Timepoint
At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement

Asking from patients

4

Description
Joint stiffness
Timepoint
At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention
Method of measurement
WOMAC questionnaire

5

Description
phyisical activity
Timepoint
At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention
Method of measurement
Asking from patients

6

Description
Knee pain
Timepoint
At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention
Method of measurement
VAS ruler, WOMAC questionnaire

Intervention groups

1

Description
Diclofenac 1% topical gel, three times a day on the l knee
Category
Treatment - Drugs

2

Description
basil oil, three times a day, topically on knee
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamzeh Clinic
Full name of responsible person
Dr Askari
Street address
Fasa University of Medical Sciences, Ebne sina square, Fasa, Fars, Iran
City
Fasa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Fasa University of Medical Sciences
Full name of responsible person
Dr. Mojtaba Farjam
Street address
Fasa University of Medical Sciences, Ebnesina square, Fasa
City
Fasa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Fasa University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Sayyed Ali Ravansalar
Position
Medical student
Other areas of specialty/work
Street address
Fasa University of Medical Sciences, Ebne sina square, fasa
City
Fasa
Postal code
7461686668
Phone
+98 71 5335 0994
Fax
Email
dr_ali_ravanasalar2012@yahoomail
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Dr.Hashempur

Position
Traditional Medicine specialist

Other areas of specialty/work

Street address
Fasa University of Medical Sciences, Ebnesina square, Fasa, Fars, Iran

City
Fasa

Postal code
7461686668

Phone
+98 71 5335 0994

Fax

Email
hashempur@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Sayyed Ali Ravansalar

Position
Medical student

Other areas of specialty/work

Street address
Fasa University of Medical Sciences, Golestan dormitory, Ebne sina square, Fasa, Fars, Iran

City
Fasa

Postal code
7461686668

Phone
00

Fax

Email
dr_ali_ravanasalar2012@yahoomail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty