# 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
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Fasa University of Medical Sciences
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Iran (Islamic Republic of)
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**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
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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
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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

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## 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*