

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of Nigella sativa oil and Dichlophenac Gel on the reduction of knee pain in patient with Osteoarthritis

#### Protocol summary

##### Study aim

Comparison of Nigella sativa and diclofenac gel on knee pain reduction due to osteoarthritis

##### Design

Two arm parallel group randomised trial with blinded postoperative outcome assessment will be performed on 70 patients during one year

##### Settings and conduct

This study will be performed on patients with knee osteoarthritis referred to the Ali ibn Abi Talib hospital in Zahedan for a period of one year. Patients are randomly divided into two groups receiving nigella sativa oil and diclofenac gel, and prescribed drugs will administrated for patients. Patients, data collectors and analyzer will not be aware of the drugs received

##### Participants/Inclusion and exclusion criteria

Including criteria consists of patients with knee osteoarthritis based on clinical and radiological criteria of the American College of Rheumatology (ACR = 2\_3); satisfaction to enter the study, and non-entry conditions include joint edema; joint inflammation; liver and kidney failure; and the use of neurological drugs.

##### Intervention groups

The intervention group rub one gram of nigella sativa oil on a knee every six hours for three weeks, and the control group rub one gram diclofenac gel on a knee every six hours for three weeks and knee pain will measured before and one hour after taking the drug.

##### Main outcome variables

Pain based on the Visual Analogue Scale (VAS); The intensity of osteoarthritis based on the KellgrenLawrence scale; Patients knee conditions based on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20181211041923N1**

Registration date: **2019-07-14, 1398/04/23**

Registration timing: **retrospective**

Last update: **2019-07-14, 1398/04/23**

Update count: **0**

#### Registration date

2019-07-14, 1398/04/23

#### Registrant information

##### Name

Marzieh Amirian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3329 5738

##### Email address

marzieh.amirian@zaums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-01-30, 1397/11/10

#### Expected recruitment end date

2019-04-30, 1398/02/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison the effect of Nigella sativa oil and Dichlophenac Gel on the reduction of knee pain in patient with Osteoarthritis

**Public title**

The effect of Nigella sativa oil and Dichlophenac Gel on the reduction of knee Osteoarthritis pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patient with knee osteoarthritis based on ACR=2\_3 and clinical standard Satisfaction to enter the study

**Exclusion criteria:**

Joint effusion Arthritis Liver and kidney failure  
Consumption of neurological drugs

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: 70

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients will not be aware of the type of medication they receive and the second executor of the research project will complete the questionnaire at the end of the treatment without knowledge of the two groups. Also the data will be analyzed without any information about group selection

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

**Street address**

Research Deputy, Zahedan University of Medical Sciences, Balochestan Blvd, Persian Gulf Expressway

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817699693

**Approval date**

2018-07-27, 1397/05/05

**Ethics committee reference number**

IR.ZAUMS.REC.1397.127

**Health conditions studied****1****Description of health condition studied**

Patients with knee osteoarthritis based on clinical and radiological criteria of the American College of Rheumatology (ACR = 2\_3)

**ICD-10 code**

80-M94

**ICD-10 code description**

Osteopathies and chondropathies

**Primary outcomes****1****Description**

Pain based on the Visual Analogue Scale (VAS)

**Timepoint**

At the beginning of the study (before the intervention) and 3 weeks after starting the drug administration

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes****1****Description**

The intensity of osteoarthritis based on the KellgrenLawrence scale

**Timepoint**

At the beginning of the study (before the intervention) and 3 weeks after starting the drug administration

**Method of measurement**

KellgrenLawrence scale

**2****Description**

Patients knee conditions based on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

**Timepoint**

At the beginning of the study (before the intervention) and 3 weeks after starting the drug administration

**Method of measurement**

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

**Intervention groups****1****Description**

Intervention group: rub one gram of nigella sativa oil on a knee every six hours for three weeks

**Category**

Treatment - Drugs

**2**

**Description**

Control group: rub one gram diclofenac gel on a knee every six hours for three weeks

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ali ibn Abi Talib hospital

**Full name of responsible person**

Mahnaz Sandooghi

**Street address**

Ali ibn Abi Talib hospital, Salamat Blvd, Persian Gulf Expressway

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zahedan

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mohsen Taheri

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Research Deputy, Zahedan University of Medical Sciences, Balochestan Blvd, Persian Gulf Expressway

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taheri@zaums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Zahedan University of Medical Sciences

**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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mahnaz Sandooghi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Province**  
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**Postal code**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available