Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 KellgreneLawrence 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

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Iran (Islamic Republic of)

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+98 54 3329 5738

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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:
Patiant 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 KellgreneLawrence scale
Timepoint
At the beginning of the study (before the intervention) and 3 weeks after starting the drug administration
Method of measurement
KellgreneLawrence 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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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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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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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