

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Evaluation and comparisson of N.oleander and Diclofenac gel in patients with knee osteoarthritis : A randomized, double-blind, controlled trial.

Protocol summary

Summary

Local analgesics for pain control can provide effective local approach. Local agents have similar efficacy without systemic side effects of oral formulations. Plants are rich and intact source of compounds and medical plants have been used without any significant side effects in traditional medicine since ages. In this study N.oleander extract was studied due to its use in traditional medicine as an analgesic in pain management. The present study is a clinical trial and double blind study. Patients with primary osteoarthritis in at least one knee, will randomly divide into two groups. Group I(30 patient) receive N.oleander gel, Group II(30 patient) Diclofenac gel. All drugs will use in simillar pakage with different code. At the beginig of the experiment and 30 days after the usage of drug the WOMAC indexes will examine.

General information

Acronym

Defli oil effect

IRCT registration information

IRCT registration number: **IRCT2013111615413N1**

Registration date: **2014-02-12, 1392/11/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-12, 1392/11/23

Registrant information

Name

Mohammad Askarfarashah

Name of organization / entity

Faculty of Traditional medicine - Tehran University of Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparisson of N.oleander and Diclofenac gel in patients with knee osteoarthritis : A randomized, double-blind, controlled trial.

Public title

Evaluation and comparisson of Defli oil and Diclofenac gel in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Out-patients aged 50-80 years who suffer osteoarthritis based on clinical and radiological criteria of ACR included participants. Exclusion criteria: Secondary osteoarthritis; trauma; Endocrine disease(hyperthyroid,hypothyroid ,Diabet); Metabolic disease; other arthritis disease; corticosteroid usage; Joint replacement; concomitant usage in glucosamine and chondroitin sulfates; Intra-articular injection during

last 3 months; usage of muscle relaxants drugs; pregnancy; anti-depression; patients suffering from heart; lung; liver; kidney and peptic ulcer and finally patients with proven hypersensitivity to drugs used in this study.

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In the present study, there were positive control group instead of placebo group.

Secondary Ids

empty

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

Ethics Committee, Faculty of Traditional Medicine,
Tehran University of Medical Sciences

Street address

Keshavarz Blv Ghods St Tehran

City

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Postal code

1417653761

Approval date

2013-10-08, 1392/07/16

Ethics committee reference number

1461/130/92/3

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

Osteoarthritis of knee

ICD-10 code

M19.0

ICD-10 code description

Primary arthrosis of other joints

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

pain

Timepoint

Before and after the treatment

Method of measurement

WOMAC questionnaire

2**Description**

stiffness

Timepoint

Before and after the treatment

Method of measurement

WOMAC questionnaire

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

physical function

Timepoint

before and after intervention

Method of measurement

questionnaire WOMAC

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

Group I: receive topical consumption of defli oil. Every 8 hour on all of site of knee for 30 days for 30days

Category

Treatment - Drugs

2**Description**

receive topical consumption of Diclofenac gel. Every 8 hour on all of site of knee for 30 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadughi Hospital

Full name of responsible person

Mohammad Askarfarashah

Street address

Ghandi Blv Shahid Sadughi Hospital
City
yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dr. Minaei; Vice chancellor for research Traditional
Medicine Faculty of Tehran University of Medica

Full name of responsible person

Dr. Minaei

Street address

Behesht Street, Vahdat eslami Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dr. Minaei; Vice chancellor for research Traditional
Medicine Faculty of Tehran University of Medica

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

Traditional Medicine Faculty, Tehran University of
Medical Sciences

Full name of responsible person

Mohammad Askarfarashah

Position

PhD candidate

Other areas of specialty/work

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Person responsible for scientific 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