

# 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

Iran (Islamic Republic of)

##### Phone

+98 21 5560 1274

##### Email address

askarfarashah.itm@gmail.com

##### 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 sulfat; 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**

Tehran

**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**

stifness

**Timepoint**

Before and after the treatment

**Method of measurement**

WOMAC questionnaire

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

physical function

**Timepoint**

befor 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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**Web page address**

## Person responsible for scientific inquiries

### Contact

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Tehran University of Medical Sciences

**Full name of responsible person**

Dr Seyyed Reza Najafizade

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Assistant Professor

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**Street address**

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## Person responsible for updating data

### Contact

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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*