

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Assessment of topical Palm date (*Phoenix dactylifera* L.) product on clinical manifestation of knee Osteoarthritis versus Diclofenac gel: A randomized clinical trial

Protocol summary

Study aim

Determination of effect of topical palm date product on clinical manifestation of knee Osteoarthritis versus Diclofenac gel

Design

Randomized controlled clinical trial with a parallel group design of 94 patient

Settings and conduct

Study will perform in Tabriz Shohada hospital. Participants after informed consent obtaining, will be placed on case and control groups according block design randomization method and receive their drugs for one month and they are under observe thru this month

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 40 to 70 ; Mild to moderate knee Osteoarthritis patients according to Kellgren-Lawrence (K-L) grading scale ; Minimum annoying pain in last (at least) 4 week before randomized selection according to VAS scale ; Pain at least in one knee in last 3 month ago. Exclusion criteria: Allergy to palm date product or Diclofenac gel ; Skin lesion on knee ; Secondary osteoarthritis ; Joint transplantation ; Oral or topical use of steroids ; Pregnancy & lactation ; Addiction ; Radiculopathy or Neuropathy ; Surgery ; Trauma

Intervention groups

The case group will receive topical palm date product for topical knee use and Control group will receive diclofenac gel for topical knee use.

Main outcome variables

1. Knee pain score according to Visual Analogue Scale and West Ontario McMaster universities questionnaire 2. Knee stiffness score according to West Ontario McMaster universities questionnaire 3. Daily activity score according to Visual Analogue Scale and West Ontario McMaster universities questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180126038510N1**

Registration date: **2018-08-25, 1397/06/03**

Registration timing: **prospective**

Last update: **2018-08-25, 1397/06/03**

Update count: **0**

Registration date

2018-08-25, 1397/06/03

Registrant information

Name

Alireza Bagherzadehkarimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3668 3374

Email address

bagerzadeha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of topical Palm date (Phoenix dactylifera L.) product on clinical manifestation of knee Osteoarthritis versus Diclofenac gel: A randomized clinical trial

Public title

Assessment of Palm date (Phoenix dactylifera L.) on clinical manifestation of knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mild to moderate knee Osteoarthritis patients according to Kellegren-Lawrence (K-L) grading scale Pain at least in one knee in last 3 month ago Minimum annoying pain in last (at least) 4 week before randomized selection according to VAS scale

Exclusion criteria:

Allergy to topical preparation of Date palm and Diclofenac gel Skin lesion on the knee Secondary Osteoarthritis as Rhuomatoid arthritis,Gout,Infectious arthritis,Metabolic arthritis,Traumatic arthritis Operative knee joint replacement Topical or systemic steroid use since 14 day before study Intraarticular steroid injection since 90 day before study Pregnancy and lactation period Alcohol and opioid addiction Radiculopathy and Neuropathy History of any kind of knee operation and trauma Utilization of other analgesic drugs since study period Nonconformity of life style according to knee health

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Block design randomization as individual by Random number table

Blinding (investigator's opinion)

Not 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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences central building , Daneshgah Ave. , Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.TBZMED.REC.1397.227

Health conditions studied

1

Description of health condition studied

Osteoarthritis of Knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Score of knee pain intensity

Timepoint

Measuring the Score of knee pain intensity at the beginning of the study and 14 and 28 days after starting use of Palm date ointment.

Method of measurement

Visual Analogue Scale And Western Ontario and McMaster Universities Osteoarthritis questionnaire

2

Description

Score of knee stiffness intensity

Timepoint

Measuring Score of knee stiffness intensity at the beginning of the study and 14 and 28 days after starting use of Palm date ointment.

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis questionnaire

Secondary outcomes

1

Description

Daily activity Score

Timepoint

Measuring of Daily activity Score at the beginning of the study and 14 and 28 days after starting use of Palm date ointment.

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis questionnaire

Intervention groups

1

Description

Intervention group: This group will expose Topical Palm date Preparation to their involved knees three times a day at a rate of one index of the index finger for 4 weeks. Preparation will prepare at the pharmacy lab at the Faculty of Traditional Medicine of Tehran University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: This group will expose Diclofenac gel to their involved knees three times a day at a rate of one index of the index finger for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada hospital

Full name of responsible person

Alireza Bagherzadehkarimi

Street address

Shohada hospital , Golshahr St., El-goli Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614754

Phone

+98 41 3389 3336

Email

maralan-bagherzadeh@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Golghasht Ave., No 2 Central Building of tabriz university of medical sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3336 9798

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Bagherzadehkarimi

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No. 3, Alley 41, Goldasht St., Zafaranieh Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166773183

Phone

+98 41 3668 3374

Fax

Email

Bagerzadeha@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Bagherzadehkarimi

Position

PhD candidate

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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