Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 controled 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 disign randomization method and receive their drugs for one month and thay are under observe thru this month

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 40 to 70 ; Mild to moderate knee Ostoarthritis patients according to Kellegren-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 jel ; Skin lesion on knee ; Scondary 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 jel for topical knee use.

Main outcome variables

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

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

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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 Ostoarthritis 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 jel 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.

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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

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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

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

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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

Latest degree
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Person responsible for updating data

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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