

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of vitamin B and E with diclofenac in reducing pain from osteoarthritis of the knee

Protocol summary

Summary

Osteoarthritis is the most common chronic disorder that causes pain and disability associated with chronic and ultimately quality of life. Various medical and non medical methods are used to treat this disease. Nowadays the effect of vitamin E and vitamin B in the treatment of rheumatic diseases is discussed. In this study, the effectiveness of vitamins B and E, along with drug diclofenac in reducing pain in patients with knee osteoarthritis will be compared and analysed. In this double-blind clinical trial, 120 patients with knee osteoarthritis referring to training clinic of rheumatology and orthopedic of Shahrekord university of medical sciences are selected and randomly divided into 3 groups of (oral diclofenac plus oral vitamin B, oral diclofenac plus oral vitamin E and oral diclofenac plus oral placebo). Pain reduction of patients was analysed based on a visual analog scale (VAS) and the extent of morning stiffness and physical function based on the Western Ontario and McMaster standard questionnaire in 3 periods of admission : (check one), two weeks and three weeks after attending the assessment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408306480N7**
Registration date: **2014-10-03, 1393/07/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-03, 1393/07/11

Registrant information

Name

Mohammad Taghi Moradi

Name of organization / entity

Shahrekord University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahrekord University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-11-10, 1393/08/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of vitamin B and E with diclofenac in reducing pain from osteoarthritis of the knee

Public title

Effectiveness of vitamin B and E in reducing pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included : having 30 to 60 years of age, a diagnosis of primary osteoarthritis of the knee by an orthopedic doctor(based on history, clinical signs, physical examination, and radiographic diagnosis of the disease and diagnostic criteria related to this disease) .

Exclusion criteria included : secondary osteoarthritis, infection or inflammatory disease of the knee joint, crystal-induced arthritis, tumors, intra-articular, knee ligament instability, previous fracture, intra-articular, knee surgery (arthroscopic or other in the past 12 months, an intra-articular injection, visual analog score less than 3 on the knee therapy in the treatment , severe concurrent disorders such as metabolic disorders and a history of certain diseases, including stroke in the past, uncontrolled hypertension, gastritis, infectious diseases, kidney failure, stomach ulcers, allergies to medications (vitamin B complex, vitamin E, vitamin B and E and the other contradictions receptor of vitamin E and B

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University of Medical Sciences

Street address

Vice Chancellor for research of Shahrekord University of Medical Sciences, Kashani Boulevard

City

Shahrekord

Postal code

Approval date

2013-12-15, 1392/09/24

Ethics committee reference number

11-8-92

Health conditions studied

1

Description of health condition studied

Osteoarthritis of the knee

ICD-10 code

M19.9

ICD-10 code description

Arthrosis, unspecified

Primary outcomes

1

Description

Morning stiffness

Timepoint

Intervention, two weeks and three weeks later

Method of measurement

Western Ontario MacMaster questionnaire

2

Description

pain

Timepoint

Intervention, two weeks and three weeks later

Method of measurement

Visual analog scale (VAS)

3

Description

Physical function

Timepoint

Intervention, two weeks and three weeks later

Method of measurement

Western Ontario MacMaster questionnaire

Secondary outcomes

1

Description

Consent to treatment

Timepoint

Three weeks after treatment

Method of measurement

questionnaire

Intervention groups

1

Description

Oral diclofenac 50 mg , 2 times daily and vitamin B complex tablets 2 times a day

Category

Treatment - Drugs

2

Description

Oral diclofenac 50 mg 2 times a day, and vitamin E at a dose of 100 mg daily

Category

Treatment - Drugs

3

Description

Oral diclofenac 50 mg 2 times a day plus a placebo pill

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational clinic of rheumatology and orthopedics

Full name of responsible person

Doctor Morteza Dehghan

Street address

Imam Ali Subspecialty Clinic, Shariati boulevard

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Dr Mahmoud Mobasheri

Street address

Vice Chancellor for research, Shahrekord University of Medical Sciences, Kashani Bld

City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrekord University of Medical Sciences

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

Shahrekord University of Medical Sciences

Full name of responsible person

Dr Morteza Dehghan

Position

Specialist in Orthopedics

Other areas of specialty/work

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Assistant Professor

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Web page address

Person responsible for updating data

Contact

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

