

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 1334 9509

##### Email address

mtmoradi@skums.ac.ir

##### 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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**Person responsible for scientific inquiries**

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**Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Doctor Morteza Dehghan

**Position**

Assistant Professor

**Other areas of specialty/work**

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**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*

