

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of the Effectiveness of Zingiber zerumbet ointment with Diclofenac Gel on clinical symptoms in patients with Knee osteoarthritis: A randomized, double-blind, controlled trial

#### Protocol summary

##### Study aim

Determine the effect of Zingiber Zerumbet (ZZ) ointment on the treatment of knee osteoarthritis

##### Design

In this research, 80 eligible patients referring to Rheumatology Clinic of Mostafa Khomeini Hospital were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups, By block randomization method; For the drug group, ZZ ointment and acetaminophen is prescribed and for the positive control group diclofenac and acetaminophen.

##### Settings and conduct

80 patients with osteoarthritis accepted by the rheumatologist based on ACR classification criteria, After receiving written consent, they are randomly assigned to two groups of drugs and positive control. Drugs will be encoding, same shape and without the name, 1 grams, four times a day for 4 weeks will prescribe to intervention groups(Both groups). Patients are allowed to take acetaminophen if they have pain; Patients two weeks after the start and after 4 weeks of treatment (end of study) are examined by the rheumatologist and the relevant data through interviews and examination of them will be collected; And the WOMAC questionnaire is completed; Also, blood tests including CBC, BUN, Cr, AST, ALT, ALP, CRP , IL1 and IL6 are taken at the beginning of the test, and the tests are repeated at the end of the 4th week.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Outpatient patients with knee osteoarthritis based on clinical criteria of ACR Exclusion criteria: Patients with Secondary osteoarthritis; Pregnancy; Joint Replacement; Knee corticosteroid injection in the past 3 months; Patients with active Renal and Liver Diseases.

##### Intervention groups

In the intervention group, the ZZ ointment administered topically in the knee area 3 times a day for 4 weeks. In the positive control group, diclofenac gel was given topically in the knee area 3 times daily for 4 weeks.

##### Main outcome variables

Knee pain according to WOMAC questionnaire; The stiffness of the joint according to the WOMAC questionnaire; Limitations of physical activity based on WOMAC questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170428033670N1**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **prospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

##### Registration date

2018-01-21, 1396/11/01

##### Registrant information

##### Name

hasan kiani

##### Name of organization / entity

shahed university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5121 4055

##### Email address

hasan-kiani@shahed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Immunology Research Center, University of shahed

**Expected recruitment start date**

2018-01-31, 1396/11/11

**Expected recruitment end date**

2018-06-19, 1397/03/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Effectiveness of Zingiber zerumbet ointment with Diclofenac Gel on clinical symptoms in patients with Knee osteoarthritis: A randomized, double-blind, controlled trial

**Public title**

Effect of Zingiber zerumbet pomade in treatment of knee arthrosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Out-patients who suffer osteoarthritis based on clinical criteria of ACR

**Exclusion criteria:**

Those who need more than 2 grams of acetaminophen daily Those who need to use other oral or intravenous analgesic Sensitivity to study drugs Patients with Secondary osteoarthritis caused by rheumatic diseases such as rheumatoid arthritis Pregnancy Joint Replacement Concomitant use of glucosamine and chondroitin sulfate Knee corticosteroid injection in the past 3 months Oral or topical use of Corticosteroid in 14 past days Other Articular corticosteroid injection in the past 1 months Mussle corticosteroid injection in the past 1months Skin Diseases in Knee Radiculopathy and Neuropathy Alcohol addicted, Drug Abuse Patients with active Renal, Liver, and Peptic Ulcer Diseases Age under 30 or over 80 years

**Age**

From **30 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The allocation of patients to Drug and Positive Control

Groups, will be done by block randomization method. Zingiber Zerumbet (ZZ) Ointment and diclofenac gel are packed in completely similar containers and in weight; Each container is identified by a code. The code and contents of containers will be recorded by a third party in a sheet. The drugs are available to the researcher in the binary blocks of ZZ and diclofenac and ultimately distributed among the patients, the investigator and the patient are not aware of the contents of the packages.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The drug containers are encoded with the same shape and weight, and are given to the researcher in binary blocks, and then given to the patient; the patient, the investigator, and the analyst in the study are blinded; The medications, are indicated for the data analyst as drug A and drug B

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahed University

**Street address**

Shahed university, Persian gulf freeway, Tehran,iran

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**Province**

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**Postal code**

3319118651

**Approval date**

2017-04-05, 1396/01/16

**Ethics committee reference number**

IR.Shahed.REC.1395.233

**Health conditions studied**

1

**Description of health condition studied**

Osteoarthritis

**ICD-10 code**

M19.9

**ICD-10 code description**

Arthrosis, unspecified

**Primary outcomes**

## 1

### **Description**

pain

### **Timepoint**

Before the intervention, the end of the second week and the end of the fourth week after the start of the intervention

### **Method of measurement**

The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) questionnaire

## 2

### **Description**

Physical Function

### **Timepoint**

Before the intervention, the end of the second week and the end of the fourth week after the start of the intervention

### **Method of measurement**

The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) questionnaire

## 3

### **Description**

Stiffness

### **Timepoint**

Before the intervention, the end of the second week and the end of the fourth week after the start of the intervention

### **Method of measurement**

The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) questionnaire

## **Secondary outcomes**

## 1

### **Description**

Interleukin 1

### **Timepoint**

Before the intervention and the end of the fourth week after the start of the intervention

### **Method of measurement**

Venous blood sample

## 2

### **Description**

Interleukin 6

### **Timepoint**

Before the intervention and the end of the fourth week after the start of the intervention

### **Method of measurement**

Venous blood sample

## **Intervention groups**

## 1

### **Description**

zingiber zerumbet pomade, Knee local use. Dosage 1 grams per use 4 times a day.

### **Category**

Treatment - Drugs

## 2

### **Description**

Plus control group: diclofenac gel group. Knee local use. Dosage 1 grams per use 4 times a day.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Mostafa Khomeini Hospital

#### **Full name of responsible person**

Hasan Kiani Ahmadabadi

#### **Street address**

Mostafa Khomeini Hospital, Italy St, Palestine Street, Tehran

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#### **Web page address**

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## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Immunology Research Center of Shahed University

#### **Full name of responsible person**

dr tuba ghazanfari

#### **Street address**

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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**  
Immunology Research Center of Shahed University  
**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**  
Shahed University  
**Full name of responsible person**  
hasan kiani Ahmadabadi  
**Position**  
MD and PhD student of Iranian Traditional Medicine  
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Medical doctor  
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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**  
No - There is not a plan to make this available  
**Informed Consent Form**  
No - There is not a plan to make this available  
**Clinical Study Report**  
No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available