

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of intra articular injection of triamcinolone in comparison with ketorolac on pain and function of patients with knee osteoarthritis, single blind clinical trial

#### Protocol summary

##### Summary

This study is designed to compare the effect of intraarticular injection of triamcinolone and ketorolac in function and activity of daily living (ADL) in patients with knee osteoarthritis. Knee osteoarthritis is the most common joint disease, but despite a variety of non-surgical procedures, so far there is no general consensus on the priority of treatment. This study is a single-blind randomized controlled clinical trial on 40 patients with mild to moderate osteoarthritis who come to Mahdieh Hospital. Patients with pain or joint swelling and radiologic findings of joint destruction since 3 months ago based on knee osteoarthritis criteria of The ACR (grade 2, 3 of Kellgren-Lawrence scale ) will be recruited. Exclusion criteria are patients with history of any intra-articular injection, knee surgery or physiotherapy in last 3 months. One injection of triamcinolone will be received in one group and ketorolac will be injected in the other one. Exercise will be prescribed for both groups. Pain, function, maximum distance walking and ADL will be measured through WOMAC and Lequesne questionnaires before intervention, 1 months and 3 months after injection

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017041633000N2**  
Registration date: **2017-04-26, 1396/02/06**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-04-26, 1396/02/06

#### Registrant information

##### Name

Masume Bayat

##### Name of organization / entity

Shahid beheshti university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2273 1112

##### Email address

bayat.masyme@sbm.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

#### Expected recruitment start date

2016-04-20, 1395/02/01

#### Expected recruitment end date

2016-12-21, 1395/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of intra articular injection of triamcinolone in comparison with ketorolac on pain and function of patients with knee osteoarthritis, single blind clinical trial

#### Public title

Comparison of triamcinolone and ketorolac in patients with knee osteoarthritis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: arthralgia since the past 3 months; radiologic evidence of articular damage (grade 2,3 of Kellgren-Lawrence scale) based on knee OA criteria of ACR and age between 45-75 years. Exclusion criteria: systemic diseases such as rheumatoid arthritis (RA), any history of intra articular injection, knee surgery or physiotherapy in the last 3 months.

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic committe of,Shahid beheshti University of Medical sciences

**Street address**

Shahid beheshti University of Medical sciences,Velenjak, Tehran, Iran

**City**

TEHRAN

**Postal code****Approval date**

2016-11-22, 1395/09/02

**Ethics committee reference number**

IR.SBMU.MSP.REC.1395.354

**Health conditions studied****1****Description of health condition studied**

Knee osteoarthritis (Gonarthrosis)

**ICD-10 code**

M17

**ICD-10 code description**

Gonarthrosis [arthrosis of knee]

**Primary outcomes****1****Description**

knee pain

**Timepoint**

before intervention,1 months & 3 months after intervention

**Method of measurement**

WOMAC questionnaire

**2****Description**

Joint Stiffness

**Timepoint**

before intervention, 1 months & 3 months after intervention

**Method of measurement**

WOMAC questionnaire

**3****Description**

function

**Timepoint**

before intervention,1 months & 3 months after intervention

**Method of measurement**

WOMAC questionnaire

**4****Description**

The maximum distance of walking

**Timepoint**

before intervention, 1 months & 3 months after intervention

**Method of measurement**

Lequesne Index

**5****Description**

Activity of daily living

**Timepoint**

before intervention, 1 months & 3 months after intervention

**Method of measurement**

Lequesne Index

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group 1: triamcinolone, knee intraarticular injection, 40 mg 1 time

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group 2: ketorolac, knee intraarticular injection, 30mg, 1 times

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mahdieh Hospital

**Full name of responsible person**

Masumeh Bayat

**Street address**

Mahdieh Hospital, Rajab Nia Street, Shisheh gar Aley, Fadaian Inslam Street, Shosh Squar, Tehran

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Physical Medicine and Rehabilitation Department of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Masumeh Bayat

**Street address**

Mahdieh Hospital, Rajab nia Street, shisheh gar alley, Fadaian Inslam Street, Shosh Squar, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Physical Medicine and Rehabilitation Department of Shahid Beheshti 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**

Shahid Beheshti Univeraity of Medical Sciences

**Full name of responsible person**

Mahsa Adili

**Position**

Resident in Physical Medicine and Rehabilitation

**Other areas of specialty/work**

**Street address**

Mahdieh Hospital, Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 21 6606 6490

**Fax**

**Email**

mahsaadili@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti Univeraity of Medical Sciences

**Full name of responsible person**

Masumeh Bayat

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Mahdieh Hospital, Tehran

**City**

tehran

**Postal code**

**Phone**

+98 21 5506 2628

**Fax**

**Email**

bayat.masyme@sbmu.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti Univeraity of Medical Sciences

**Full name of responsible person**

Mahsa Adili

**Position**

Resident in Physical Medicine and Rehabilitation

**Other areas of specialty/work**

**Street address**

Shahid Modarres Hospital, Saadat Abad street, Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 216606490

**Fax**  
**Email**  
mahsaadili@gmail.com  
**Web page address**

## 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*  
**Data Dictionary**  
*empty*