Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 intera-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)

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Email address

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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 intera 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 siences

Street address

Shahid beheshti University of Medical siences,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 intraarticuar 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

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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