

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Efficacy of Intramuscular Injection of Calcitonin on Pain & Functional Status of Patients with Knee Osteoarthritis

Protocol summary

Study aim

The effect of intramuscular injection of calcitonin on the functional status of patients with osteoarthritis of the knee

Design

A controlled clinical trial with parallel groups, one-way blind, randomized, phase 3-2 was performed on 40 patients and a simple individual randomization method with sealed envelope tools was used.

Settings and conduct

This randomized controlled trial will be designed and implemented during August-November 2020 in the pain clinic of Imam Hossein (AS) Hospital (Tehran, Iran). The physician who evaluates patients at the beginning and two months later does not know the patient group (case group or control group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 35-75 years; knee pain during past 6 months; at least two clinical symptoms of joint inflammation based on ACR criteria for osteoarthritis (either clinical or clinical plus radiographic).
Exclusion criteria: unwilling to participate in the study; history of cardiovascular, renal, hepatic or gastrointestinal disease; history of coagulopathy; currently using DMOADS agents (hydroxychloroquine, sulfasalazine, methotrexate, cyclosporine, azathioprine); pre-existing allergies to calcitonin; history of intra-articular injection into the affected knee within 3 months before study enrollment; those having already received total knee arthroplasty; recent history of substance abuse and those who considered unable to reliably report outcome measures due to cognitive impairment.

Intervention groups

All patients are randomly divided into two groups: one group is injected calcitonin (50 IU/ml intramuscularly) once a week for 4 consecutive weeks, and in case of pain, AcetaGel (500mg) and piroxicam (0.5% topical gel) are prescribed, and the second group is given only conservative treatments including AcetaGel (500mg) and

piroxicam are given.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130518013364N9**

Registration date: **2021-01-17, 1399/10/28**

Registration timing: **retrospective**

Last update: **2021-01-17, 1399/10/28**

Update count: **0**

Registration date

2021-01-17, 1399/10/28

Registrant information

Name

Mehrdad Taheri

Name of organization / entity

Shahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 7756 7840

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

2020-07-26, 1399/05/05

Actual recruitment end date

2020-12-14, 1399/09/24

Trial completion date

2020-12-22, 1399/10/02

Scientific title

Efficacy of Intramuscular Injection of Calcitonin on Pain & Functional Status of Patients with Knee Osteoarthritis

Public title

Efficacy of Intramuscular Injection of Calcitonin on Pain & Functional Status of Patients with Knee Osteoarthritis

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 35-75 years knee pain during past 6 months At least two clinical symptoms of joint inflammation based on ACR criteria for osteoarthritis

Exclusion criteria:

unwillingness to participate in the study History of cardiovascular disease History of renal disease History of hepatic disease History of gastrointestinal disease History of coagulopathy History of intra-articular injection into the affected knee within 3 months before Currently using DMOADS agents (hydroxychloroquine, sulfasalazine, methotrexate, cyclosporine, azathioprine) Pre-existing allergies to calcitonin Previous knee arthroplasty Recent history of substance abuse Those who cannot report the result reliably due to cognitive impairment

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization is done with sealed envelope tools in such a way that the letters A and B are inserted in the envelopes and patients are asked to select an envelope that the intervention group A and the group B will be as control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The physician who evaluates patients two months later, does not know the patient's group(case or control group).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway, Shahid Beheshti University Of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2020-07-12, 1399/04/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.362

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

Osteoarthritis of knee

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

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

pain

Timepoint

At the beginning of the study (before the intervention) and two months after

Method of measurement

VAS

2**Description**

WOMAC Index

Timepoint

At the beginning of the study (before the intervention) and two months after

Method of measurement

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group is injected calcitonin (50 IU/ml intramuscularly) once a week for 4 consecutive weeks, and in case of pain, AcetaGel (500mg) and piroxicam (0.5% topical gel) are prescribed.

Category

Treatment - Other

2

Description

Control group: The control group is given maintenance treatments, including AcetaGel and piroxicam (0.5% topical gel).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital's pain clinic

Full name of responsible person

Mehrdad Taheri

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Shahid Madani street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarqi

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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

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehrdad Taheri

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

Not applicable

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

Not applicable