Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

Phone
+98 21 7756 7840

Email address
m.taheri@sbmu.ac.ir

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
Street address
Shahid Madani street
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
m.taheri@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarqi
Street address
Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
1985717434
Phone
+98 21 2243 9951
Email
mpd@sbmu.ac.ir
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
Anesthesiology
Street address
Shahid Madani street-Imam Hossein Hospital
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
m.taheri@sbmu.ac.ir
Web page address

Person responsible for scientific 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

Anesthesiology

Street address

Shahid Madani street-Imam Hossein Hospital

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

m.taheri@sbmu.ac.ir

Person responsible for updating data

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

Anesthesiology

Street address

Shahid Madani street-Imam Hossein Hospital

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

m.taheri@sbmu.ac.ir

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