

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the efficacy of osvalin, piascladine and placebo in the improvement of pain in patients with knee osteoarthritis

Protocol summary

Study aim

Determination of the efficacy of osvalin, piascladine and placebo in patients with knee osteoarthritis

Design

Three arm parallel group controlled randomized trial with blinded post treatment care and outcome assessment

Settings and conduct

Patients with knee osteoarthritis in Rasoul-e-Akram hospital, Tehran enrolled . These patients were divided into three groups and received osvalin, piascladine and placebo for three months respectively. The treatment outcomes were evaluated at 4, 8 and 12 weeks. Patients and doctors blinded of distribution of patients in the groups.

Participants/Inclusion and exclusion criteria

Patients with knee osteoarthritis

Intervention groups

Patients with knee osteoarthritis

Main outcome variables

Pain relief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180316039112N2**

Registration date: **2019-08-05, 1398/05/14**

Registration timing: **retrospective**

Last update: **2019-08-05, 1398/05/14**

Update count: **0**

Registration date

2019-08-05, 1398/05/14

Registrant information

Name

Tayeb Ramim

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 0000

Email address

tayebiramim@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

2019-02-20, 1397/12/01

Actual recruitment end date

2019-04-30, 1398/02/10

Trial completion date

2019-04-30, 1398/02/10

Scientific title

Comparison of the efficacy of osvalin, piascladine and placebo in the improvement of pain in patients with knee osteoarthritis

Public title

Effect of Osvalin and Piascladine on the treatment of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with knee osteoarthritis

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **36**

Actual sample size reached: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

The "Balanced Block Randomization" method was performed using statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients participating in the study and the physician, as well as those responsible for evaluating the outcome, were kept blind to study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Rasool Akram hospital., Maziar Mansori Ave., Sattarkhan Ave

City

تهران

Province

Tehran

Postal code

1445613131

Approval date

2018-02-17, 1396/11/28

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9611288001

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M19-9

ICD-10 code description

Arthrosis, unspecified

Primary outcomes

1

Description

pain

Timepoint

Measuring the pain at the beginning of the study (before the intervention) and 4, 8 and 12 weeks after starting the drug

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group I: Osvalin, the Shafatab Drug company produces in the form of a syrup. It prescript in a 5 ml daily.

Category

Treatment - Drugs

2

Description

Intervention group II: Piascledine, a 300 mg herbal capsule, made in France. It prescript in a one pill daily.

Category

Treatment - Drugs

3

Description

Control group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Tayeb Ramim

Street address

Satarkhan St, Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

tayebramim@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

Street address

Sattar khan Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

motevalian@iums.ac.ir

Web page address

http://vcr.iums.ac.ir/

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Tayeb Ramim

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

Street address

Rasool Akram hospital, Maziar mansori Ave., Sattar
khan Ave., Tehran.

City

تهران

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

tayebramim@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Tayeb Ramim

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

Street address

Rasool Akram hospital, Maziar mansori Ave., Sattar
khan Ave., Tehran.

City

تهران

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

tayebramim@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Tayeb Ramim

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

Street address

Rasool Akram hospital, Maziar mansori Ave., Sattar
khan Ave., Tehran.

City

تهران

Province

Tehran
Postal code
1445613131
Phone
+98 21 6651 5001
Email
tayebramim@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

انتشار مقاله

When the data will become available and for how long

2020-2021

To whom data/document is available

ALL

Under which criteria data/document could be used

knowledge purpose

From where data/document is obtainable

journal

What processes are involved for a request to access data/document

submission

Comments