

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Study of analgesic effects of topical tramadol 5% on Osteoarthritis pain: A randomized, placebo control, double blind clinical trial

Protocol summary

Summary

To evaluate the effect of topical tramadol on osteoarthritis pain relief, this randomized, double blind, placebo control clinical trial is designed. To this purpose, tramadol powder prepared and 5% cream in eucerin base is made. Sixty number of patients referred to rheumatology clinic were selected and randomized into two 30 persons group to receive one of interventions. All patients with moderate to severe osteoarthritis pain based on Visual analog scale, enrolled in the study and patients with hypersensitivity to tramadol, history of seizures or using anticonvulsant medicines were excluded. In addition to conventional oral treatment of diclofenac tablets, patients received tramadol or placebo cream twice a day for a month. At the end of the intervention, the grade of pain reevaluated and recorded in the questionnaire. Patients are allowed to stop the treatment anytime and whenever they cannot tolerate the side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609143014N14**

Registration date: **2016-12-22, 1395/10/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-22, 1395/10/02

Registrant information

Name

Shahram Ala

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1354 3083

Email address

sala@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mazandaran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of analgesic effects of topical tramadol 5% on Osteoarthritis pain: A randomized, placebo control, double blind clinical trial

Public title

Study of analgesic effects of topical tramadol on Osteoarthritis pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient with moderate and severe osteoarthritis pain Exclusion criteria: Patients with hypersensitivity reaction to tramadol; Patient with history of seizure; Patients taking oral anticonvulsant drug

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization is done using random number table. We give a code number to each patient that shows the group each patient is allocated to. The list of patients and their code numbers is kept secret until the end of the trial. In this way neither the patient nor the researchers know whether it is drug or placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University Medical Sciences

Street address

Moalem Sq.Vice chancellor of research

City

Sari

Postal code

Approval date

2016-09-20, 1395/06/30

Ethics committee reference number

IR.Mazums.Rec.95-2373

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M15, M16,

ICD-10 code description

Polyarthrosis, Coxarthrosis [arthrosis of hip], Gonarthrosis [arthrosis of knee], Arthrosis of first carpometacarpal joint, Other arthrosis

Primary outcomes

1

Description

Pain

Timepoint

Before intervention; One month after intervention

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Side effects

Timepoint

After intervention

Method of measurement

quality Questionnaire

Intervention groups

1

Description

Intervention: Tramadol 5% cream, twice daily for one month

Category

Treatment - Drugs

2

Description

Control: Cream without active ingredient, twice daily for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rhmatology Clinic of Baghbanian

Full name of responsible person

Dr Shahram Ala

Street address

Khazar Sq.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Mazandaran

University of Medical Sciences

Full name of responsible person

Dr Ahmadali Enayatifar

Street address

Payambar Azam University Complex, Mazandaran
University of Medical Sciences, Faculty of Pharmacy,
Km 20 Khazar Abad Road

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Mazandaran 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

Mazandaran University of Medical Science, Faculty of
Pharmacy

Full name of responsible person

Dr Shahram Ala

Position

Clinical pharmacy specialist, associated professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Mazandaran University of Medical Science, Faculty of
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Full name of responsible person

Mahila Monajati

Position

Resident of clinical pharmacy

Other areas of specialty/work

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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