

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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**

**Street address**

Payambar Azam University Complex, Mazandaran  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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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## 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*