

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the efficacy of Tetonal drug in comparison with Meloxicam on pain relief and functional improvement of patient with knee osteoarthritis

#### Protocol summary

##### Study aim

Evaluation of the efficacy of teltonel drug in comparison with meloxicam in reducing pain and improving the function of patient with knee osteoarthritis

##### Design

The clinical trial has two treatment groups, with parallel, randomized groups

##### Settings and conduct

A randomized clinical trial of two treatment groups, with parallel groups, randomized on patients with knee osteoarthritis referred to Imam Reza Clinic, Chamran and Shahid Rajaei Hospital of Shiraz

##### Participants/Inclusion and exclusion criteria

Patients with knee osteoarthritis who consent to the intervention and have no history of drug allergy

##### Intervention groups

Group A Treatment with Meloxicam Group B treatment with Teltonal drug

##### Main outcome variables

The scores from the The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAK), Oxford Knee Score (OKS) and Visual analogue scale( VAS) questionnaires will be measured together

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191031045291N1**

Registration date: **2020-01-26, 1398/11/06**

Registration timing: **retrospective**

Last update: **2020-01-26, 1398/11/06**

Update count: **0**

##### Registration date

2020-01-26, 1398/11/06

#### Registrant information

##### Name

Najmeh Rajabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3627 0861

##### Email address

n.rajabi.1372@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2019-12-07, 1398/09/16

##### Expected recruitment end date

2020-01-20, 1398/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Evaluation of the efficacy of Tetonal drug in comparison with Meloxicam on pain relief and functional improvement of patient with knee osteoarthritis

#### Public title

Evaluation of the efficacy of Tetonal drug in comparison with Meloxicam on pain relief and functional improvement of patient with knee osteoarthritis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Adult patient aged 40-70 Clinical diagnosis of

osteoarthritis Patient had been symptomatic for one month No periarticular disease

**Exclusion criteria:**

Collagen vascular disease Radiculopathy Brucella Knee truma Bmi >42 Bleeding tendency History of drug reaction

**Age**

From **40 years** old to **70 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

No information

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to randomize the study, Blocked and cluster random method is used. Patients are also clustered by age and severity of symptoms. The list is compiled by a computer with the same block length and the clinic secretary divides the patients according to the list.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Faghihi hospital ,Ave.,zand Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Approval date**

2019-04-15, 1398/01/26

**Ethics committee reference number**

IR.SUMS.MED.REC.1398.271

**Health conditions studied**

**1**

**Description of health condition studied**

Knee osteoarthertitis

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

knee pain

**Timepoint**

Before the intervention, the second, fourth and eighth weeks after the intervention

**Method of measurement**

visual analogue scale (VAS) score, estern Ontario and McMaster Universities Osteoarthritis Index(WOMAC ) and Oxford Knee Score (OKS) questionnaires

**2**

**Description**

Knee function

**Timepoint**

Before the intervention, the second, fourth and eighth weeks after the intervention

**Method of measurement**

visual analogue scale (VAS) score, estern Ontario and McMaster Universities Osteoarthritis Index(WOMAC ) and Oxford Knee Score (OKS) questionnaires

**3**

**Description**

knee stiffness

**Timepoint**

Before the intervention, the second, fourth and eighth weeks after the intervention

**Method of measurement**

visual analogue scale (VAS) score, estern Ontario and McMaster Universities Osteoarthritis Index(WOMAC ) and Oxford Knee Score (OKS) questionnaires

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group 1: Meloxicam from Iran Daroo company ,15 mg daily for 10 days

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group 2: daily use of two tablets of Telnonal

from Razak Company for one month

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Emam reza clinic

**Full name of responsible person**

Hamidreza farpour

**Street address**

Namazi square

**City**

Shiraz

**Province**

Fars

**Postal code**

7134871473

**Phone**

+98 71 3212 7000

**Email**

farporh@sums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shiraz university of medical sciences

**Full name of responsible person**

Younes Qasemi

**Street address**

Shiraz university of medical sciences, Zand Blvd.

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+98 71 3230 5884

**Email**

farporh@sums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Najmeh Rajabi

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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Shahid Faghihi hospital, Zand Blvd.

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**Province**

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7134844119

**Phone**

+98 71 3230 5884

**Email**

n.rajabi.1372@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hamidreza Farpor

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Najmeh Rajabi

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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**Email**

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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**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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