

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Non-steroids Anti-inflammatory Drugs on Treatment of Patients with Ocular pain and Migraine Headache induced trochleitis

Protocol summary

Study aim

To determine the effect of non-steroids anti-inflammatory drugs on treatment of patients with ocular pain and migraine headache induced trochleitis

Design

This is a clinical trial (before-after) phase 3 study that will perform on 35 to 40 patients with ocular pain and migraine headache induced trochleitis.

Settings and conduct

This study is carried out at Kowsar Hospital in Sanandaj, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with ocular pain and migraine headache with confirmed diagnosis of trochleitis by MRI
Exclusion criteria: patients with glaucoma; patients with Uveitis

Intervention groups

This is a before-after study that conduct on only one group. Patients with ocular pain and migraine headache with confirmed diagnosis of trochleitis by MRI undergo one of the NSAIDs (Ibuprofen) for two weeks.

Main outcome variables

Headache, , Tenderness, Tearing, Photophobia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180114038350N1**

Registration date: **2018-04-20, 1397/01/31**

Registration timing: **retrospective**

Last update: **2018-04-20, 1397/01/31**

Update count: **0**

Registration date

2018-04-20, 1397/01/31

Registrant information

Name

Khaled Rahmani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30

Expected recruitment end date

2018-01-30, 1396/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Non-steroids Anti-inflammatory Drugs on Treatment of Patients with Ocular pain and Migraine Headache induced trochleitis

Public title

Effect of Non-steroids Anti-inflammatory Drugs on Treatment of Patients with Ocular pain and Migraine Headache induced trochleitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Ocular pain and Migraine Headache induced trochleitis

Exclusion criteria:
 Patients with glaucoma Patients with Uveitis Patients with Scleritis Patients with Conjunctivitis Patients with Keratitis Patients with optic neuritis

Age
 From **20 years** old

Gender
 Both

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: **40**
 Actual sample size reached: **33**

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Kurdistan University of Medical Sciences

Street address
 Pasdaran Blvd

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 Sanandaj

Province
 Kurdistan

Postal code
 6617713446

Approval date
 2018-03-13, 1396/12/22

Ethics committee reference number
 IR.MUK.REC.1396.358

Health conditions studied

1

Description of health condition studied
 trochleitis

ICD-10 code
 H57.10

ICD-10 code description
 Ocular pain, unspecified eye

Primary outcomes

1

Description
 Pain

Timepoint
 2 weeks, one month and 6 months after treatment initiation.

Method of measurement
 By using VAS instrument

Secondary outcomes

1

Description
 Photophobia, Supraduction gaze pain, Reading pain, Itching, Tearing

Timepoint
 2 weeks, one month and six months after treatment initiation

Method of measurement
 Clinical examination and assessment of signs and symptoms using asking the patients and recording in the check list

Intervention groups

1

Description
 Intervention group: Patients with Ocular pain and migraine headache induced trochleitis Treatment or intervention include administering Ibuprofen 400 mg (every 6 to 8 hours) for a period of two weeks to one month.

Category
 Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
 Kawsar educational hospital

Full name of responsible person
 Ghazal Kamali

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kurdistan 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**

Kurdistan University of Medical Sciences

Full name of responsible person

Khaled Rahmani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

In case of publisher journal request, data would be sent to the journal.

When the data will become available and for how long

During the publication of paper and 6 months after publish

To whom data/document is available

Editor of the journal that publish the paper and academic researchers with permission of correspondence author

Under which criteria data/document could be used

Data can only used to meta analysis with permission of correspondence author

From where data/document is obtainable

The correspondence author of the study

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

By sending the mail to the correspondence author

Comments