

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison between Celecoxib and Prednisolone in bridge stage therapy following medication overuse headache

Protocol summary

Summary

Celecoxib has not been abuse widely as a pain relief drug for headache. Our aim of this study was Comparison between Celecoxib and Prednisolone in bridge stage therapy following medication overuse headache. Double-blind randomized clinical trial was done in patients admitted to a private headache clinic in Tehran; Iran at 2012. Patients with 18-65 years old with > 15 days headache per month were studied. Prednisone as a 75mg, 50 mg, 30 mg, 25 mg and 10 mg/day (every 3 days) and celexcib as a 100mg three times, twice and one time/day (every 5 days) was administered. Headache days, headache intensity, headache duration, analgesic consumption due to severe headaches and drug side effects were assessed. Was used the visual analog scale to determine the severity of the pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061211560N6**

Registration date: **2013-09-10, 1392/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-10, 1392/06/19

Registrant information

Name

Tayeb Ramim

Name of organization / entity

Sina Trauma and Surgery Research Center, Tehran
University of Medical Sciences

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Tehran University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Celecoxib and Prednisolone in bridge stage therapy following medication overuse headache

Public title

Withdrawal treatment in medication overuse headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 18-65 years old; headache more than 15 days per month; regular using of two drugs or more for symptomatic therapy more than 3 month; progressive headache; no underlying disease; no pregnancy. Exclusion criteria: no follow up and stopping of using drugs.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science

Street address

Hemat gateway, Central division of Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

91/d/130/1428

Health conditions studied

1

Description of health condition studied

Medication Overuse Headache

ICD-10 code

G44.4

ICD-10 code description

Drug-induced headache

Primary outcomes

1

Description

Headache time

Timepoint

Start of treatment, 2 weeks following start of treatment

Method of measurement

Hour

2

Description

Headache

Timepoint

Start of treatment, 2 weeks following start of treatment

Method of measurement

Visual Analogue Scale

3

Description

Headache days

Timepoint

Start of treatment, 2 weeks following start of treatment

Method of measurement

Days

Secondary outcomes

1

Description

Drug adverse reaction

Timepoint

Start of treatment, 2 weeks following start of treatment

Method of measurement

Hstory

Intervention groups

1

Description

Prednisone as a 75mg, 50 mg, 30 mg, 25 mg and 10 mg/day (every 3 days)

Category

Treatment - Drugs

2

Description

Celecoxib as a 100mg three times, twice and one time/day (every 5 days)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Elahe Taghvaii Zahmat kesh, Neurology assistant

Street address

Sina Hospital, Imam Khomeini St, Hasan Abad Sq

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.

City

Tehran

Grant name**Grant code / Reference number**

1428/130/91/3

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

Yes

Title of funding source

Deputy of Research, Tehran 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**

Sina Hospital, Tehran University of Medical Sciences

Full name of responsible person

Elahe Taghvaii Zahmat kesh

Position

Neurology assistant

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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