Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 devision 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, 2weeks 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
Celexcib 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/د
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
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Position
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Person responsible for updating data

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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