

# 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

Iran (Islamic Republic of)

##### Phone

+98 21 6312 0000

##### Email address

tayebiramim@sina.tums.ac.ir

##### 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

**Other areas of specialty/work****Street address**

Imam khomeni St, Hasan Abad Sq, Sina hospital

**City**

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**Postal code****Phone**

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elahetaghvaii@tums.ac.ir

**Web page address**

## Person responsible for scientific

## 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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## Person responsible for updating data

**Contact****Name of organization / entity**

Sina Hospital, Tehran University of Medical Sciences

**Full name of responsible person**

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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*