Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluate the comparative effectiveness of three therapeutic drug regimen for the treatment of a withdrawal headache in patients with medication overuse headache, referring to the neurology clinic

Protocol summary

Study aim
comparing the effect of three therapeutic drug regimen for the treatment of a withdrawal headache in patients with medication overuse headache

Design
The randomized clinical trial with three groups

Settings and conduct
The study will be conducted as a randomized clinical trial. Participants in the study will be among patients referred to a neurology clinic of Imam Khomeini Hospital in Urmia in 2018. The patients with identified headache under the title of MOH will be included based on the inclusion criteria.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with ages18 to 50 years old, no specific disease history, no pregnancy, patients with a headache more than 15 days in the month, regular use history of one or more medications for more than three months, lack of platelet disorders. Exclusion Criteria: No referral for the upcoming follow-up, arbitrary discontinuation of the drug

Intervention groups
1-celexib group 2-prednisolon group 3-prednisolon plus celexib group

Main outcome variables
Headache severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181014041334N1**
Registration date: **2018-12-02, 1397/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-02, 1397/09/11**
Update count: **0**

Registration date
2018-12-02, 1397/09/11

Registrant information

Name
Arash Mosarrezaii

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-06, 1397/08/15

Expected recruitment end date
2019-11-06, 1398/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluate the comparative effectiveness of three therapeutic drug regimen for the treatment of a withdrawal headache in patients with medication overuse headache, referring to the neurology clinic

Public title
Comparing the effectiveness of three therapeutic drug regimen for the treatment of a withdrawal headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 18 to50 year Patients with headache more than 15 days per month A history of regular use of one or more symptomatic treatment medications over a period of more than a month, including ergotamine, tryptan, combination of analgesic drugs (simple and combination), tryptones, ergotamine and narcotics (more than 10 days per month for more than 3 months), or analgesic drugs Simple such as acetaminophen or NSAIDs (10 days per month in regular three months) A headache that progresses or gets worse in the course of drug abuse lack of mental psychological illness no pregnancy No previous history or disease has been detected not having platelet disorders

Exclusion criteria:

lack of referral for the follow up Arbitrary discontinuation of patient medication

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For each group, there will be 10 envelopes for men and 10 envelopes for women containing the group number (20 envelopes for each group). The Clinic Clerk will randomly pick up an envelope from one group for delivery to the eligible patient. For women, this should be the same. At the same time, one Female person within a group should be entered in parallel with one male one, until finally, 10 men and 10 women will be enrolled in the study within each group.

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

Urmia Medical Science University Ethical committee

Street address

Resalat

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-05-30, 1397/03/09

Ethics committee reference number

IR.UMSU.REC.1397.094

Health conditions studied

1

Description of health condition studied

Medication Overuse Headache (MOH)

ICD-10 code

G44

ICD-10 code description

Other headache syndromes

Primary outcomes

1

Description

Headache severity

Timepoint

15 days

Method of measurement

VAS

2

Description

Headache duration

Timepoint

daily

Method of measurement

headache duration (days)

Secondary outcomes

1

Description

Drug dependence reduction

Timepoint

15 days

Method of measurement

Used Drug Dosage

Intervention groups

1

Description

Intervention group: celecoxib (100 mg, Cap, Iran, Tehran, Daru Pars, celecoxib 100 mg three times daily for the

first five days, 100 mg twice daily (five days later) and 100 mg once a day (five The next day)

Category

Treatment - Drugs

2

Description

Intervention group: Prednisolone Tablets (Aburaihan Pharmaceutical, Iran, Tehran, .Co, 50 mg, 5 mg) 75 mg (three first days) 50 mg (three days later) 30 mg (three The next day (25 mg three days later) and 10 mg (the last 3 days)

Category

Treatment - Drugs

3

Description

Intervention group: celecoxib 100 mg three times daily + 75 mg prednisolone for the first 4 days, celecoxib 100 mg twice daily + 50 mg prednisolone for the second 4 days, celecoxib 100 mg once daily + 25 mg prednisolone for 4 days, 100 mg once daily + 10 mg prednisolone for 3 last day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Clinic of Urmia Emam Khomein Hospital

Full name of responsible person

Dr. Arash Mosarrezaii

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Ershad Ave

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Web page address

http://imam.umsu.ac.ir/index.aspx?fkeyid=&siteid=19&pageid=13220

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.iraj Mohebbi

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Web page address

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr Afshin Chehreghani

Position

Neurology Assisstant

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not 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
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

Title and more details about the data/document
Moh data

When the data will become available and for how long
year

To whom data/document is available
scientific valid researchers

Under which criteria data/document could be used
with authority

From where data/document is obtainable
Dr chehregani email

What processes are involved for a request to access data/document
should be requested via email or valid scientific web site such as research gate

Comments