Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of Medication Overuse Headache and Compression Between the Effect of Perdnisolone - nortyliptilin and prednisolone- sodium valproate

Protocol summary

Summary

Prednisolone-Sodium Valproate has not been extensively abused by the patients as a pain reliever medication in treating headaches The aim of study is analyzing the efficacy of Prednisolone-Sodium Valproate and comparing it with Prednisolone-Nortriptyline in reduction of headache severity during the withdrawal period of the medicine. The study uses a randomized, double-blind clinical trial methodology on patients of a private clinic in Babol during in 2016 between 15 to 60 year old patients, who are suffering from headache more than 15 days in month, are enrolled in the trial. Subjects are divided into two random groups. Both groups are prescribed with Prednisolone 50mg/1kg for 5 days. Additionally, a random group receive Sodium Valproate 200mg every 12 hours, and the other group is given Nortriptyline 10mg every 24 hours, for two months. The factors such as days of headache, headache severity, duration of headache, taking other pain relievers due to severe pain, and drugs side effects are investigated. Visual analog scale (VAS) is used to determine the severity of headaches.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060718479N1**
Registration date: **2016-07-08, 1395/04/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-08, 1395/04/18

Registrant information

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Name of organization / entity

Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Medication Overuse Headache and Compression Between the Effect of Perdnisolone - nortyliptilin and prednisolone- sodium valproate

Public title

Treatment of stage withdrawal headaches caused by abuse drugs.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 15-60 years; daily headache present on 15day/month; regular overuse for >3 month of 1 or more acute/symptomatic treatment

drugs; headache has developed during medication overuse. Exclusion criteria: Age<15 years, severe systemic pathologic associated to chronic headache; major psychiatric disorder such as major depression; hypochondriasis; Contraindication or sensitivity to drugs use in study; pregnancy or lactation

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Babol University of Medical Sciences, Deputy of research & technology

Street address
University of Medical Sciences, Ganjafroz Street

City
Babol

Postal code

Approval date
2013-11-09, 1392/08/18

Ethics committee reference number
3326

Health conditions studied

1

Description of health condition studied
Headache caused by drug abuse

ICD-10 code
G44.4

ICD-10 code description
Drug-induced headache

Primary outcomes

1

Description
Number of headache attack s

Timepoint
Before treatment, after 2 month of treatment

Method of measurement
number

2

Description
Remission headache

Timepoint
Before treatment, after 2 month of treatment

Method of measurement
Qualitative and based on the positive or negative.

3

Description
The days of headache

Timepoint
Before treatment, after 2 month of treatment

Method of measurement
day

Secondary outcomes

1

Description
Drug side effect

Timepoint
At the start of the intervention, after 2 month of treatment

Method of measurement
questionnaire

Intervention groups

1

Description
Prednisolone 50mg/1kg for 5 days. Additionally, a random group will receive Nortriptyline 10mg every 24 hours

Category
Treatment - Drugs

2

Description
Prednisolone 50mg/1kg for 5 days. Additionally, a random group will receive Sodium Valproate 200mg every 12 hours for 2 month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid Specialized Clinic.
Full name of responsible person
Ebrahim Valinejad shubi
Street address
Babol University of Medical Sciences, Ganjafroz Street, Babol
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Babol University of Medical Sciences
Full name of responsible person
Ali Akbar Moghadamnia
Street address
Babol University of Medical Sciences, Ganjafroz Street, Babol
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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
Vice Chancellor for Research of Babol 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

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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