

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the efficacy of intravenous sodium valproate and acetaminophen(paracetamol) in attacks of headaches

Protocol summary

Study aim

Comparison of the efficacy of intravenous sodium valproate and acetaminophen(paracetamol) in attacks of headaches

Design

Patients with acute headache attack were admitted to emergency department and neurology department of Amiral-Momenin Hospital enter this study. Study is a double-blind and clinical trial. The sample size is 70 people.

Settings and conduct

Patients with acute headache attack were admitted to emergency department and neurology department of Amiral-Momenin Hospital enter this study. Study is a double-blind and clinical trial. Simple individual randomization with random number table in division of groups in two groups A and B. This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normal systemic and neurological examinations, 20 to 50 yeras Exclusion criteria: Allergy to acetaminophen, Hyperammonium ,lack of cooperation

Intervention groups

In the first group, we inject valproate 400 milligram intravenously and infused slowly, and second group we inject ampule of acetaminophen (paracetamol, apothel) of 500 milligram.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N102**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of intravenous sodium valproate and acetaminophen(paracetamol) in attacks of headaches

Public title

Comparison of the efficacy of intravenous sodium valproate and acetaminophen in attacks of headaches

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Normal systemic and neurological examinations 20 to 50 years

Exclusion criteria:

Allergy to acetaminophen Hyperammonium Lack of cooperation

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random number table in division of groups in two groups A and B. Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment: Numbered drug containers

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

848176941

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.ARAKMU.REC.1397.260

Health conditions studied

1

Description of health condition studied

Migraine headach

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

pain

Timepoint

One and six hours after the start of the study

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first group, we inject valproate 400 milligram intravenously and infused slowly

Category

Treatment - Drugs

2

Description

Intervention group: In second group we inject ampule of acetaminophen (paracetamol, apothel) of 500 milligram.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Fardin Faraji

Street address

Sardasht, Basij square, Amiralmomenin hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandadegan

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Behzadi nia

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Niloofer Mir majidi

Position

medicine student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Fardin faraji

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments