Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Name of organization / entity
Arak University of Medical Sciences

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Iran (Islamic Republic of)

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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 yeras
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 Committe 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 squre,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
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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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Person responsible for updating data

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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