Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of IV Sodiom Valproate in contrast to IV Dexametazon for treatment of patient with severe Migraine Headache

Protocol summary

Study aim

Comparsion of effect of 1200 mg IV Sodiom Valproate and 8 mg IV Dexametazone in treatment of Severe Migrain Headache ,

Design

After approval for participating in the study, patients will be numbered from 101 to 208 sequentially (medications will be prepared by a pharmacist in uniform and uni-shape packages and will be randomized and numbered from 101 to 208). based on the numbers each package will be allocated to each patient. Medications will be infused by a nurse. This study is a double blind clinical trial with intervention and control groups. Sample size is 108 (54 in each group).

Settings and conduct

Golestan Hospital , Ahwaz ,Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients who come with : Acute migrainous headache which VAS score equal or more than 4 , Age equal or more than 18 to less or equal 58 years old and body weight equal or more than 50 to less or equal 80 kg. Exclusion criteria : Pregnancy or lactation , Presens of systemic disease(Cardiovascular ,Pulmonary ,Metabolic ,Liver &Renal insufficiency ,Cancer ,Seizure , Use of Anticoagolants & Anticonvulsants drugs . Use of any Sedative , Hypnotic drugs recently upto 4 h, Use of Ergot &Triptamin component recently to 24 h. Positive hypersensitivity to Dexamethazon & Sodiom Valproate

Intervention groups

Control group: 8 mg Dexametasone; (in 150 ml N/S during 10 mins). Intervention group: 1200 mg Na Valproate (in 150 ml N/S during 10 mins).

Main outcome variables

Decrease of Migrainous Headache severity and related symptoms ,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180223038830N1**
Registration date: **2019-07-20, 1398/04/29**
Registration timing: **retrospective**

Last update: **2019-07-20, 1398/04/29**
Update count: **0**

Registration date

2019-07-20, 1398/04/29

Registrant information

Name

Mohammadreza Dadkhahtehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of IV Sodiom Valproate in contrast to IV Dexametazon for treatment of patient with severe Migraine Headache

Public title
Effect Of IV Sodiom Valproate in Migraine , Effect of IV Dexametazon in Migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The chief complaint of patients is acute headache. Positive past history of Migraine headache Intensity of headache equal or more than four base on VAS score Age equal or more than 18 to less or equal than 58 years old. Body weight equal or more than 50 to less or equal than 80 kg.
Exclusion criteria:
BP more than 160/100 mmHg SBP less than 100 mmHg PR less than 50 /Min Pregnancy or lactation Presens of systemic disease(Cardiovascular ,Pulmonary ,Metabolic ,Liver &Renal insufficiency ,Cancer ,Seizure) Use of Anticoagolant & Anticonvulsant & Antimetobolit drugs. Use of any IV sedative drugs in 4 h. ago. Use of Ergot &Triptamin component recently to 24 h. Positive history of hypersensitivity to Dexamethazon & Sodiom Valproate
Age
From **18 years** old to **58 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization , based on ETCETERA Version 3.26 ,Balanced randomization [module A3]
Blinding (investigator's opinion)
Double blinded
Blinding description
The research pharmacist will prepare 108 uniform and unishape boxes , which 54 those medications are 1200 mg Na Valproate ,and the rest of 54 medications are 8 mg Dexametason that will be placed into sequentially numbered from 101 to 208 , in order determined by balanced allocation of 108 subjects to groups A and B . Patients that will be enrolled to the study , if they would have inclusion criteria and not have any exclusion criteria , who will be numberd from 101 to 208 respectively .
Placebo
Not used
Assignment
Parallel
Other design features
In this study , range of patients , body weight (50- 80 kg) is one of our parameters , so that , this has not been in any other same studies.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahwaz JondiShapour University of Medical Sciences
Street address
Farvardin St.
City
Ahwaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2017-12-19, 1396/09/28
Ethics committee reference number
IR.AJUMS.REC.1396.718

Health conditions studied

1

Description of health condition studied
Migraine without aura(common migraine)
ICD-10 code
G43.0
ICD-10 code description
Migraine without aura

2

Description of health condition studied
Migraine with aura (classic migraine)
ICD-10 code
G43.1
ICD-10 code description
Migraine with aura

Primary outcomes

1

Description
Decrease of Migrainuos Headache severity and related symptoms,
Timepoint
0.5 , 1 , 2 hour after use of medication,
Method of measurement
VAS score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Sodiom Valproate (Depakine), manufactured by Sanofi S.P.A./Italy , 1200 mg in 250 cc Normal Salin , administerd intravenously over 15 minutes for the patients.
Category
Treatment - Drugs

2

Description
Control group: Dexamethasone ,manufactured by Iran Hormone Pharmaceuticals , 8 mg in 250 cc Normal Salin ,administerd intravenouslyover 15 minutes for the patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital , Ahwaz
Full name of responsible person
Mohammad Reza Dadkhah Tehrani
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Sponsors / Funding sources

1

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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Reza Dadkhah Tehrani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable