

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

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

Protocol summary

Study aim

Comparison of effect of 1200 mg IV Sodium Valproate and 8 mg IV Dexametazone in treatment of Severe Migraine 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 Anticoagulants & 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 & Sodium Valproate

Intervention groups

Control group: 8 mg Dexametazone; (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)

Phone

+98 61 3374 3001

Email address

dadkhahtehrani.m@ajums.ac.ir

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 Sodium 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

Street address

Farvardin

City

Ahwaz

Province

Khouzestan

Postal code

61357-33118

Phone

+98 61 3374 3001

Fax

+98 61 3374 3030

Email

dadkhahtehrani.m@ajums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Tirandaz

Street address

Farvardin

City

Ahwaz

Province

Khouzestan

Postal code

61357-33118

Phone

+98 61 3374 3001

Fax

+98 61 3374 3030

Email

Fatemetirandaz@gmial.com

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

Emergency Medicine

Street address

Farvardin

City

Ahwaz

Province

Khouzestan

Postal code

61357-33118

Phone

+98 61 3374 3001

Fax

+98 61 3374 3030

Email

dadkhahtehrani.m@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Fateme Tirandaz

Position

Emergency medicine specialist

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Farvardin

City

Ahwaz

Province

Khouzestan

Postal code

61357-33118

Phone

+98 61 3374 3001

Fax

+98 61 3374 3030

Email

Fatemetirandaz@gmail.com

Person responsible for updating data

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

Emergency Medicine

Street address

Farvardin

City

Ahwaz

Province

Khouzestan

Postal code

61357-33118

Phone

+98 61 3374 3001

Fax

+98 61 3374 3030

Email

dadkhahtehrani.m@ajums.ac.ir

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