Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The Evaluation of Valproic acid Pharmacokinetic Key Parameters as a Seizure Prophylactic Agent Following Subarachnoid Hemorrhage

Protocol summary

Summary

This study is a prospective observational study that is going to be conducted at General and Emergency ICUs of Sina hospital and Internal ICU of Imam Khomeini hospital.25 adult patients with subarachnoid hemorrhage; GCS ≤ 12 will be taken valproic acid as a seizure prophylactic agent for seven days.Patients who have seizure during the study will excluded. We consider 1200 mg intravenous sodium valproate as a loading dose that will be diluted in at least 50 ml of normal saline solution and will be infused over 60 minutes with a maximum speed of 20 mg/min and then the patients will taken 400 mg intravenous sodium valproate Q8h for three days and then the patients will taken 500 mg sodium valproate orally for other four days Q8h. Patients will be studied for a week and blood Samples will be collected after 4 hours, 12 hours, before the third dose ,before the XII dose and before the last dose. Immediately after sampling,the blood samples will be centrifuged for 10 minutes (3000rpm/min) to collect plasma .Serum samples will be maintained at - 80 ° C until analysing time.Analysis of serum samples containing valproic acid will be conducted by GC-MASS (Gas chromatography–mass spectrometry) method.The pharmacokinetic key parameters of the drug include the volume of distribution, plasma concentraion ,clearance and main metabolites of the drug(2-ene-valproate and 4-ene valproate) will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091113572N3**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name
Mohammadreza Rouini

Name of organization / entity
Tehran University of Medical Sciences, Faculty of Pharmacy

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Recruitment status

Recruitment complete

Funding source

1-Financial supporting from Tehran University of Medical Sciences-accepted as an university scientific project 2-Providing all medicine by coble darou that related to Sanofi aventis pharmaceutical company

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluation of Valproic acid Pharmacokinetic Key Parameters as a Seizure Prophylactic Agent Following Subarachnoid Hemorrhage

Public title

Evaluation the serum level of valproic acid in subarachnoid hemorrhage patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with subarachnoid hemorrhage; GCS ≤ 12; Age over 18 Exclusion Criteria: Scr≤1.5 mg/dl or urine output>0.5cc/Kg/hr; Plattlet count<100,000; INR≥2; Albumin<3; Age >18; Liver Function Test>3×Normal Range; Mean Arterial Pressure<70; Occurance of seizure during the study; Previous CNS diseases such as Parkinson's, Multiple sclerosis, CNS tumors, Infections involving the brain and CNS; History of using anti-epileptic drugs; Pregnancy; History of urea cycle disorders

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods st, Enghelab st, Tehran, Ethical Committee of Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2013-06-16, 1392/03/26

Ethics committee reference number

91-04-33-20322

Health conditions studied

1

Description of health condition studied

subarachnoid hemorrhage

ICD-10 code

160

ICD-10 code description

ruptured cerebral aneurysm

Primary outcomes

1

Description

Total serum concentration

Timepoint

after 4 hours, 12 hours, before the third dose ,before the XII dose and before the last dose

Method of measurement

blood sampling from cv-line/GS-MASS

Secondary outcomes

1

Description

unbound serum concentration

Timepoint

after 4 hours, 12 hours, before the third dose ,before the XII dose and before the last dose

Method of measurement

formula

2

Description

volume of distribution

Timepoint

after 4 hours, 12 hours, before the third dose ,before the XII dose and before the last dose

Method of measurement

formula

3

Description

clearance

Timepoint

after 4 hours, 12 hours, before the third dose ,before the XII dose and before the last dose

Method of measurement

formula

4

Description

2-ene-valproate as a metabolite

Timepoint

after 4 hours, 12 hours, before the third dose ,before the XII dose and before the last dose

Method of measurement
GS-MASS

5

Description
4-ene-valproate as a metabolit
Timepoint
after 4 hours, 12 hours, before the third dose ,before the XII dose and before the last dose
Method of measurement
GS-MASS

Intervention groups

1

Description
we consider 1200 mg intravenous sodium valproate as a loading dose that will be diluted in at least 50 ml of normal saline solution and will be infused over 60 minutes with a maximum speed of 20 mg/min and then the patients will taken 400 mg intravenous sodium valproate Q8h for three days and then the patients will taken 500 mg sodium valproate orally for other four days Q8h. Patients will be studied for a week and blood Samples will be collected after 4 hours, 12 hours, before the third dose ,before the XII dose and before the last dose
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Emergency and General ICU of Sina Hospital
Full name of responsible person
Dr.Mojtaba Mojtahedzadeh
Street address
Sina Hospital, Hasanabad square, Emam Khomeini st, Tehran
City
Tehran

2

Recruitment center
Name of recruitment center
General ICU of Emam Khomeini Hospital
Full name of responsible person
Dr.Mohammadtaghi Beyg Mohammadi
Street address
Emam Khomeini Hospital, Bolvar Keshavarz st, Valiasr square, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University Of Medical Sciences
Full name of responsible person
Dr.Mohammad Sharifzadeh
Street address
Faculty of Pharmacy, Tehran University of Medical Sciences, Ghods st, Enghelab st, Tehran
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University Of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Cobel Darou Company
Full name of responsible person
Dr.Shokrollah Memarian
Street address
39, Alvand st, Arzhantin square, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cobel Darou Company
Proportion provided by this source
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

Contact

Name of organization / entity
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Full name of responsible person
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Position
Full Professor

Other areas of specialty/work

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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