

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparison of the seizure control with intravenous sodium valproate and Phenobarbital in children who referred to Ali-Ebn-Abitaleb hospital in Zahedan in 2012-2013.

Protocol summary

Summary

Comparison of the seizure control with intravenous sodium valproate and Phenobarbital in children who referred to Ali-Ebn-Abitaleb hospital in Zahedan in 2012-2013. Randomized clinical trial. Study sample: Children with seizure who referred to Ali-Ebn-Abitaleb hospital in Zahedan in 2012-2013 we enrolled children who were experiencing convulsions while attending emergency rooms and whose seizures were not controlled by a bolus of intravenous diazepam (0.2 mg/kg) within 5 min. We excluded children with a history of adverse reactions to sodium sodium valproate or similar drugs, a history of uncontrolled bleeding, thrombocytopenia, active hepatic disease, cardiac rhythm disturbances orthostatic hypotension, or syncope. Consecutive patients were enrolled and randomised in quaternary blocks to receive either intravenous sodium valproate rapid loading or intravenous phenobarbital. after random allocation of patients to blocks, each patient received the medication package designed for that block. Phenobarbital was given at loading dose of 20 mg/kg via an infusion pump at a rate not faster than 60-100 mg/min. Sodium valproate was given at loading dose of 20 mg/kg, diluted in 20 ml saline. The main outcome variable was termination of all convulsive activity, which should be achieved within 20 min of starting anticonvulsant infusion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071113956N1**

Registration date: **2013-09-11, 1392/06/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-11, 1392/06/20

Registrant information

Name

Saeedeh Yaghoobi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 1326 0407

Email address

zahedan.medical@gmail.com

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the seizure control with intravenous sodium valproate and Phenobarbital in children who referred to Ali-Ebn-Abitaleb hospital in Zahedan in 2012-2013.

Public title

Comparison of the drugs seizure control

Purpose

Treatment

Inclusion/Exclusion criteria

we enrolled children who were experiencing convulsions while attending emergency rooms and whose seizures were not controlled by a bolus of intravenous diazepam (0.2 mg/kg) within 5 min. We excluded children with a history of adverse reactions to sodium sodium valproate or similar drugs, a history of uncontrolled bleeding, thrombocytopaenia, active hepatic disease, cardiac rhythm disturbances orthostatic hypotension, or syncope.

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

zahedan university of medical sciences

Street address

pardis zahedan university of medical science zahedan, dr hesabi circle, zahedan

City

zahedan

Postal code

Approval date

2012-08-13, 1391/05/23

Ethics committee reference number

91-913

Health conditions studied

1

Description of health condition studied

Seizure

ICD-10 code

G40-47

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

Response to treatment

Timepoint

once after intervention then 20 minutes later

Method of measurement

View seizure control or lack of control

2

Description

recovery time

Timepoint

once after intervention then 20 minutes later

Method of measurement

measurement duration of seizure control with time unit(minute)

Secondary outcomes

empty

Intervention groups

1

Description

With the drug phenobarbital dose of 20 mg per kg body weight, single dose, in control group, within 20 minutes of seizure control is considered a positive response

Category

Treatment - Drugs

2

Description

With the drug sodium valproate dose of 20 mg per kg body weight, single dose, in intervention group, within 20 minutes of seizure control is considered a positive response

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Aliebne Abitaleb hospital

Full name of responsible person

Saeedeh Yaghoobi, MD, pediatric resident

Street address

aliebne abitaleb hospital, khaliye fars blvd,zahedan

City

Zahedan

Fax

+98 54 1341 4561

Email

zahedan.medical@gmail.com

Web page address

www.zaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Assistant zahedan University of Medical Sciences

Full name of responsible person

Research Assistant zahedan University of Medical Sciences

Street address

Pardis zahedan university of medical science,dr hesabi circles,zahedan

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Assistant zahedan University of Medical Sciences

Proportion provided by this source

100

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**

Zahedan University of Medical Sciences

Full name of responsible person

Saeedeh Yaghoobi

Position

MD, pediatric resident

Other areas of specialty/work**Street address**

Zahedan University of Medical Sciences, Pardis, Dr Hesabi Squ., Zahedan

City

Zahedan

Postal code

98167-43463

Phone

+98 54 1341 4570

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Saeedeh Yaghoobi

Position

MD

Other areas of specialty/work**Street address**

Zahedan University of Medical Sciences, Pardis, Dr Hesabi Squ., Zahedan

City

Aahedan

Postal code

98167-43463

Phone

+98 54 1341 4570

Fax

+98 54 1341 4561

Email

zahedan.medical@gmail.com

Web page address

www.zaums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Saeedeh Yaghoobi

Position

MD

Other areas of specialty/work**Street address**

Zahedan University of Medical Sciences, Pardis, Dr Hesabi Squ., Zahedan

City

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Postal code

98167-43463

Phone

+98 54 1341 4570

Fax

+98 54 1341 4561

Email

zahedan.medical@gmail.com

Web page address

www.zaums.ac.ir

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