

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of continuous infusion of sodium valproate and midazolam in children status epilepticus

Protocol summary

Summary

The purpose of this study is to compare clinical efficacy and safety of intravenous midazolam and sodium valproate infusion in treatment of status epilepticus in children. In a randomized clinical trial study all of children with status epilepticus whom are admitted in Boo-Ali sina hospital and treated with drip of intravenous midazolam or sodium valproate. Seventy patients are evaluated in two groups of 35. Inclusion criteria: 1. Minimum age 3 month and maximum 14 years old; 2. Absence of renal or hepatic dysfunction, shock, atrial or ventricular block; 3. No drug history of valproate or midazolam therapy in control of status epilepticus; 4. Normal range of CBC, BS, Ca, Na, K, BUN, Cr, SGOT, SGPT at beginning of treatment; 5. No control of status epilepticus with first line drugs such as diazepam, Phenytoin and Phenobarbital. Exclusion criteria: 1. All children with acute or chronic liver disease; 2. All children with metabolic disease; 3. Seizure in children with trauma; 4. All children with coagulation dysfunction then response to treatment and complications are compared Pharmaceutical.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206101808N4**
Registration date: **2016-02-14, 1394/11/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-14, 1394/11/25

Registrant information

Name

Ali Abbaskhanian

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 15 1223 3010

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aabbaskhanian@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of continuous infusion of sodium valproate and midazolam in children status epilepticus

Public title

Comparison of sodium valproate and midazolam in children status epilepticus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Minimum age 3 month and maximum 14 years old ; Absence of renal or hepatic dysfunction, shock, atrial or ventricular block ; No drug history of valproate or midazolam therapy in control of status epilepticus ; Normal range of CBC, BS, Ca, Na, K, BUN, Cr, SGOT, SGPT at beginning of treatment ; No control of

status epilepticus with first line drugs such as diazepam, Phenytoin and Phenobarbital. exclusion criteria: all children with acute or chronic liver disease ; all children with metabolic disease ; seizure in children with trauma ; all children with coagulation disfunction

Age

From **3 months** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Mazandaran University of Medical Sciences and Health Services

Street address

Imam Sq, Joybar 3way, Start of valiye asr highway

City

Sari

Postal code

Approval date

2016-01-26, 1394/11/06

Ethics committee reference number

IR.MAZUMS.REC.94-911

Health conditions studied

1

Description of health condition studied

status epilepticus

ICD-10 code

G41

ICD-10 code description

Status epilepticus

Primary outcomes

1

Description

status epilepticus treatment

Timepoint

before prevention and 24 hours after prevention

Method of measurement

questionarie

Secondary outcomes

1

Description

complications of treatment

Timepoint

during first 72 hours of prevention

Method of measurement

questionarie

Intervention groups

1

Description

Intervention: valproate Loading: 20mg/kg, then 20-30mg/kg/24 hr

Category

Treatment - Drugs

2

Description

Control: midazolam Loading: 0/15mg/kg, then 1-6µg/kg/min

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali sina hospital - pediateric Department

Full name of responsible person

Dr Ali Abbaskhanian

Street address

Emam sq - Pasdaran Blv

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Center of Mazandaran University of Medical

Sciences and Health Services

Full name of responsible person

Dr Ahmad Ali Enayati

Street address

Moalem sq. Sari

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Center of Mazandaran University of Medical Sciences and Health Services

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

Mazandaran University of Medical sciences and Health services

Full name of responsible person

Motahareh Kheradmand

Position

Master of science in nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of medical sciences and Health services

Full name of responsible person

Dr Ali Abbaskhanian

Position

Pediatric neurologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of medical sciences and Health Services

Full name of responsible person

Dr Kobra Sheidaee

Position

Pediatrician

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

Web page address

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