Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of continuous infusion of sodium valporate 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 disfunction, 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 disfunction 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)

Phone

+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 valporate and midazolam in children status epilepticus

Public title

Comparison of sodium valporate 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 disfunction, 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 Univercity of Medical sciences and Health ervices

Full name of responsible person
Motahareh Kheradmand

Position
Master of science in nursing

Other areas of specialty/work

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Moallem square

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Pediatric neourologist

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Person responsible for updating data

Contact

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Mazandaran Univercity of medical sciences and Health Services

Full name of responsible person
Dr Kobra Sheidaee

Position
Pediatrician

Other areas of specialty/work

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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