

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Propofol and Thiopental in the treatment of refractory Status Epilepticus

Protocol summary

Summary

Forty patients aged 2 months to 18 years with Status Epilepticus and resistant to therapy with Phenobarbital, Phenytoin and Midazolam, admitted to PICU are enrolled in the study. Consecutive odd and even numbers are assigned to them. Propofol and Thiopental are administered to odd and even numbered, respectively. Propofol is given as a bolus of 1-2 mg/kg followed by continuous infusion of 1-2 mg/kg/hr. If necessary, the dose is raised by 2 mg/kg/hr every 10 minute to a maximum of 8 mg/kg/hour. Thiopental is given as a bolus of 1 mg/kg followed by continuous infusion of 2 mg/kg/hour. If necessary, the dose is raised by 2 mg/kg/hour till maximum dose of 10mg/kg/hour. If convulsion is not controlled after receiving the maximum dose of the drug, the patient will be put on another option. The goal of treatment with Propofol is disappearance of clinical seizures and epileptic activity on the EEG for 12-24 hours. The goal of treatment with thiopental is complete control of seizures for 12-24 hours with a burst suppression pattern on the EEG. Side effects are regularly monitored, and infusion is stopped if side effects emerged. In patients treated with Propofol, special attention is paid to Liver function tests, triglycerides, Creatine Kinase, and blood gas analyses. In patients treated with thiopental, special attention is paid to respiratory, circulatory, and infectious complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707231349N1**
Registration date: **2009-05-02, 1388/02/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-05-02, 1388/02/12

Registrant information

Name

Saeedeh Haghbin

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71164744298

Email address

haghbins@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2008-09-12, 1387/06/22

Expected recruitment end date

2009-09-12, 1388/06/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Propofol and Thiopental in the treatment of refractory Status Epilepticus

Public title

Comparison of Propofol and Thiopental in the treatment of refractory Status Epilepticus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Refractory Status Epilepticus. Exclusion

criteria: hypotension, hypoxia, sepsis, liver failure, renal failure, heart disease

Age

To 18 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Status Epilepticus: one convulsion lasting for more than 30 min or two or more seizures without full recovery of consciousness between them. Refractory status epilepticus: prolonged status convulsion without response to Benzodiazepines, Phenobarbital and Phenytoin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand Blvd,

City

shiraz

Postal code

Approval date

2008-06-10, 1387/03/21

Ethics committee reference number

87-4044

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G41

ICD-10 code description

Status epilepticus

Primary outcomes

1

Description

Convulsion control

Timepoint

During admission

Method of measurement

Time (hours) to stop convulsion

2

Description

Convulsion control

Timepoint

During admission (EEG every 24 hr)

Method of measurement

Time (hours) to see burst suppression appearance on EEG

Secondary outcomes

1

Description

Complication of treatment (metabolic acidosis, fatty liver, hypoxia)

Timepoint

blood gas analyses: every hour, blood chemicals: twice a day, others: every other day

Method of measurement

laboratory tests

2

Description

Time of mechanical ventilation

Timepoint

During admission

Method of measurement

Time (hours) of mechanical ventilation

3

Description

PICU stay

Timepoint

During admission

Method of measurement

Number of PICU admission days

Intervention groups

1

Description

Thiopental: 1mg/kg/hour intravenous continuous infusion

Category

Treatment - Drugs

2

Description

Propofol: 2mg/kg/hour intravenous continuous infusion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Intensive Care Unit, Nemazee Hospital

Full name of responsible person

Saeedeh Haghbin

Street address

Zand Blvd, Nemazee Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, Vice chancellor for Research

Full name of responsible person

Street address

Zand blvd, central building of Shiraz University of Medical Sciences

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences, Vice chancellor for Research

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

Shiraz University of Medical Sciences, Medical school

Full name of responsible person

Saeedeh Haghbin

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Assistant professor / Pediatric Intensivist

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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