Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 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

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Name of organization / entity
Shiraz University of Medical Sciences
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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
labratory tests

2

Description
Time of mechanical ventilation

Timepoint
During admission

Method of measurement
Time (hours) of mecahanical 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 continous infusion

Category
Treatment - Drugs

2

Description
Propofol: 2mg/kg/hour intravenous continous 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 chanceller 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 chanceller 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
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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