Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of intravenous midazolam drip with intermittent intravenous diazepam in the treatment of refractory serial seizures in children

Protocol summary

Summary

Serial seizures may have side effects on brain. In our hospital, the first approach as the routine approach for refractory serial seizure is admission of the patient in the Pediatric Intensive Care Unit (PICU) and starting intravenous midazolam infusion. Limited PICU services in some remote hospitals were the main drawback of this approach serial seizures may have side effects on brain. In our hospital, the first approach as the routine approach for refractory serial seizure is admission of the patient in the Pediatric Intensive Care Unit (PICU) and starting intravenous midazolam infusion. Limited PICU services in some remote hospitals were the main drawback of this approach. The aim of this study was achievement of a new method for treatment of patients with serial seizures when transfer to the PICU is not possible. this study included all admitted children with refractory serial seizures in Mofid hospital, which is a referral center for pediatric neurological diseases, The diagnostic criteria for refractory serial seizures in this study was defined as four generalized tonic-clonic or complex partial seizures per day with a three-fold increase over usual seizure frequency within a two-day period that received at least two appropriate intravenous, intramuscular or oral antiepileptic drugs with no decrease to less than the pretreatment level in seizure frequency. Patients were randomly assigned to midazolam or diazepam groups. We survey patients in both groups for duration of admission, stay in ICU, side effects and need to mechanical ventilation. The aim of this study was achievement of a new method for treatment of patients with serial seizures when transfer to the PICU is not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012082210634N1**

Registration date: **2012-09-20, 1391/06/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-09-20, 1391/06/30

Registrant information

Name

Afshin Fayazi

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1264 0075

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of Research and Technology of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous midazolam drip with intermittent intravenous diazepam in the treatment of refractory serial seizures in children

Public title
Intermittent intravenous diazepam in the treatment of refractory serial seizures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Children > 1 mo old; Children with serial seizures; Children with refractory epilepsy and no response to conventional drugs during first 6 hours
Exclusion criteria Drug side effects; Exacerbation of seizure during treatments; Status Epilepticus
Age
From **1 year** old to **15 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Velenjak Street, Shahid Chamran High Way , Shahid Beheshti University of Medical Sciences
City
Tehran
Postal code
Approval date
2010-10-10, 1389/07/18
Ethics committee reference number
88-01-146-6383-3571

Health conditions studied

1

Description of health condition studied
Serial Seizures
ICD-10 code
G40.9
ICD-10 code description
Epilepsy, unspecified

Primary outcomes

1

Description
Duration of seizure control
Timepoint
Hour
Method of measurement
Observation

Secondary outcomes

1

Description
Duration of stay in hospital and PICU
Timepoint
Day
Method of measurement
Observation

Intervention groups

1

Description
In cases group: Intravenous diazepam was administered every 3 hours (0.2 mg /kg).
Category
Treatment - Drugs

2

Description
In control group: Midazolam was administered as an intravenous bolus dose (0.2mg/kg), followed by continuous intravenous infusion (1-10 µg/kg per min).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Hospital
Full name of responsible person
Dr.Parvaneh Karimzadeh
Street address
Shariati Av
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Research and Technology of shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Mohammad Rahmati
Street address
Velenjak Street, Shahid Chamran High Way, Shahid Beheshti University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of Research and Technology of shahid Beheshti 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
Hamedan University of Medical Sciences
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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