

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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)

###### Phone

+98 81 1264 0075

###### Email address

afshin\_fay@yahoo.com

##### 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

**Full name of responsible person**

dr. Afshin Fayazi

**Position**

Assistant Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Email**

afshin\_fay@yahoo.com

**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*