

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparing buccal midazolam vs. intravenous diazepam in control of acute seizures in children: a randomized clinical trial.

Protocol summary

Summary

In this study we want to compare the efficacy and complications of buccal midazolam with intravenous diazepam in the treatment of acute seizures in Iranian children. Materials and Methods: This is a prospective randomized controlled clinical trial in which 92 patients are randomly assigned to receive buccal midazolam or intravenous diazepam. The trial is conducted in the pediatric emergency unit or neurologic ward of Mofid children hospital , a referral center for neurologic emergency in Tehran. Patients aged 6 months to 14 years, presented with acute convulsion, were randomly assigned to receive buccal midazolam or intravenous diazepam. The primary outcome of this study is the time when seizure stopped after drug administration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902293967N1**

Registration date: **2011-08-14, 1390/05/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-14, 1390/05/23

Registrant information

Name

Seyed Hassan Tonekaboni

Name of organization / entity

Mofid children hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2290 9559

Email address

tonekaboni@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Pediatric Neurology Research Center

Expected recruitment start date

2007-12-24, 1386/10/03

Expected recruitment end date

2008-12-23, 1387/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing buccal midazolam vs. intravenous diazepam in control of acute seizures in children: a randomized clinical trial.

Public title

Comparing buccal midazolam vs. intravenous diazepam in control of acute seizures in children.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all children aged 6 months to 14 years old presenting with acute generalized seizure in emergency ward or pediatric neurology ward are randomly assigned to receive buccal midazolam or intravenous diazepam. Exclusion criteria: seizures due to head trauma or known metabolic causes (hypoglycemia, hypocalcemia)

Age

To **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 92

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti Medical University

Street address

Ethics committee, Shahid Beheshti Medical University, next to Taleghani hospital, Evin, Chamran free way

City

Tehran

Postal code

Approval date

2007-12-23, 1386/10/02

Ethics committee reference number

001

Health conditions studied

1

Description of health condition studied

Acute childhood seizure

ICD-10 code

G40

ICD-10 code description

Epilepsy

Primary outcomes

1

Description

The time it takes to control seizure

Timepoint

The time it takes to control seizure is measured once after using IV diazepam vs. buccal midazolam

Method of measurement

Time measured in minute, evaluated from start to the end of seizure

Secondary outcomes

1

Description

Potential side effects

Timepoint

Potential side effects of the two drugs

Method of measurement

Clinical evaluation of possible side effect

Intervention groups

1

Description

Intervention group1: after establishing an intravenous route diazepam is infused 0.2-0.3 mg/kg to control seizure

Category

Treatment - Drugs

2

Description

Intervention group2: buccal midazolam is administered to children with convulsion based upon the age as follow: 2.5 mg for children aged 6-12 months 5mg for children 1-4 years 7.5 mg for children5-9 years 10 mg for children 10 years and older

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pediatric Neurology Research Center

Full name of responsible person

Dr. Ghofrani

Street address

PNRC Ofiice, 2nd floor, Official building, Mofid Children Hospital, Shariati Avenue, befor Mirdamad

St.
City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Pediatric Neurology Research Center
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
 Pediatric Neurology Research Center
Full name of responsible person
 Dr. Seyed Hassan Tonekaboni
Position
 Associate professor and pediatric neurologist
Other areas of specialty/work
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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