

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Comparing the Efficacy and Side Effects of Intranasal Midazolam and Intravenous Diazepam in children with seizure attack

Protocol summary

Summary

Acute seizure attack might cause mortality and morbidity among patients, so reliable methods to control the seizure- preferably applicable at home- should be developed. This study was performed as a randomized non-blind clinical trial on 60 patients coming to Imam Ali Hospital, Zahedan, Iran. The patients were 2 months to 15 years old coming to our emergency department suffering from an acute seizure episode and fulfilled the including criteria. All of these patients were randomly divided into case and control groups, so there were 30 patients in each group. Intranasal midazolam was administered 0.2 mg/kg equally dropped in both nostrils for case group and intravenous diazepam was administered 0.3mg/kg via IV line for control group. After both treatments the time needed to control the seizure was registered by the practitioner. Pulse rate and O2 saturation was recorded at patient's entrance and in minutes 5 and 10 after drug administration.

General information

Acronym

None

IRCT registration information

IRCT registration number: **IRCT201012105358N1**

Registration date: **2011-01-05, 1389/10/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-05, 1389/10/15

Registrant information

Name

Mohsen Javadzadeh

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

The research administration of Zahedan University of Medical Sciences

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2009-05-22, 1388/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy and Side Effects of Intranasal Midazolam and Intravenous Diazepam in children with seizure attack

Public title

Comparing Midazolam and Diazepam in childhood seizures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria Inclusion criteria were age between 2 months and 15 years, suffering from acute seizure episode and presence of parents (in order to acquire consent). Exclusion criteria Having an IV line before coming to our center, being administered with any kind of anticonvulsant drug, having any sign of upper

respiratory tract infection.

Age

To 15 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Zahedan, Khaliije Fars Highway, The University
Campus

City

Zahedan

Postal code

Approval date

2007-11-22, 1386/09/01

Ethics committee reference number

1995-86

Health conditions studied

1

Description of health condition studied

epilepsy

ICD-10 code

G40

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

Time needed to stop seizure

Timepoint

Once, After giving the medication

Method of measurement

Clinical observation

Secondary outcomes

1

Description

Heart rate

Timepoint

Twice, at 5, and 10 minutes after medication

Method of measurement

Counting the pulse rate

2

Description

Hb Oxygen saturation

Timepoint

Twice, At 5 & 10 minutes after medication

Method of measurement

Pulse Oxymetry

Intervention groups

1

Description

Intranasal midazolam was administered 0.2 mg/kg
equally dropped in both nostrils for case group.

Category

Treatment - Drugs

2

Description

Intravenous diazepam was administered 0.3mg/kg via IV
line for control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Imam-Ali Hospital

Full name of responsible person

Mohsen Javdazadeh, Child Neurologist, Assistant
Professor

Street address

Shahid Madani avenue, Imam Hossein Hospital,
Pediatrics ward

City

Tehran

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Email

m.javadzadeh@sbmu.ac.ir;
mohsen.javadzadeh@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Research administration of Zahedan university of
medical sciences

Full name of responsible person

Dr Mohammad Bakhshani (at the time of performing
the study)

Street address

Imam Khomeini avenue, Baharan Hospital

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Research administration of Zahedan 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mohsen Javadzadeh

Position

Child Neurologist, Assistant professor in pediatrics
department

Other areas of specialty/work**Street address**

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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