

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Efficacy of Intramuscular Midazolam versus Rectal Gel Diazepam in controlling status epilepticus in children: A randomized double-blind clinical trial

Protocol summary

Summary

The aim of this study is determination of the efficacy of intramuscular midazolam in comparison with the rectal gel diazepam in controlling the status epilepticus in children. A double blind, randomized, clinical trial in 80 children with age of one month and up to 16 years in two centers. Inclusion criteria: Age of one month and up to 16 years, Status epilepticus more than 5 minutes. Exclusion criteria: Having an established IV access on arrival to emergency departments, Use of benzodiazepines prior arrival to the emergency departments, Serial seizures and having a history of serious adverse reactions to IM midazolam or rectal diazepam. In midazolam group, IM midazolam will be used with a dose of 0.3 mg/kg (Maximum 15 mg) following by rectal tube placebo and IM placebo following by rectal diazepam will be used with a dose of 0.5 mg/kg (Maximum 10 mg). Midazolam will be injected into the left quadriceps muscle if the child is younger than two years and if the child is older than two years the left deltoid muscle will be considered for injection. In the diazepam group, the rectal gel tube will be inserted into the rectum and to ensure that the drug is administered correctly, the buttocks will be kept high together for 5 min to prevention expulsion and then the tube will be removed. The primary outcome is stopping seizures within less than 10 minutes and a lack of recurrence of motor activity 60 minutes after the seizure. Secondary outcomes include side effects of medications, Time of prescribe medication to cessation seizure, Time from arrival to emergency department until prescribe medication, And time arrival of patients to the emergency department until the seizure stopped.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031529801N3**
Registration date: **2017-11-05, 1396/08/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-05, 1396/08/14

Registrant information

Name

Saeid Sadeghiyan

Name of organization / entity

Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 937 134 4848

Email address

b_sadeghian@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Intramuscular Midazolam versus Rectal Gel Diazepam in controlling status epilepticus in children: A randomized double-blind clinical trial

Public title

Efficacy of Intramuscular Midazolam versus Rectal Gel Diazepam in controlling status epilepticus in children: A randomized double-blind clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of one month and up to 16 years, Status epilepticus more than 5 minutes during arrival to emergency department. Exclusion criteria: Having an established IV access on arrival to emergency departments, Use of nasal and rectal benzodiazepines prior arrival to the emergency departments by parents or paramedics, Parents discontent to participate in the study, Serial seizures without recovery of consciousness between seizures, and having a history of serious adverse reactions to IM midazolam or rectal diazepam.

Age

From **1 month** old to **16 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study, the randomization will be done using a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz University of Medical Sciences

Street address

Golestan street, Shahre Daneshgahi, Vice chancellor for research of Ahwaz University of Medical Sciences, Ahvaz

City

Ahvaz

Postal code

-

Approval date

2017-07-29, 1396/05/07

Ethics committee reference number

IR.AJUMS.REC.1396.411

Health conditions studied

1

Description of health condition studied

Status epilepticus in children

ICD-10 code

G40-G47

ICD-10 code description

G40.3

Primary outcomes

1

Description

Stopping of all motor activity after drug administration without recurrence within 60 min after stopping of seizure

Timepoint

After drug administration until 60 minutes later

Method of measurement

Visual analogue scale and digital chronometer

Secondary outcomes

1

Description

Time to cessation after medication

Timepoint

Once and after prescribing the medication

Method of measurement

Digital chronometer

2

Description

Time from arrival to administer medication

Timepoint

Once and after prescribing the medication

Method of measurement

Digital chronometer

3

Description

Time to cessation after arrival

Timepoint

Once and after prescribing the medication

Method of measurement

Digital chronometer

4

Description

Medication side effects

Timepoint

After drug administration

Method of measurement

Monitoring of vital signs and symptoms developed up to 60 minutes after intervention

Intervention groups

1

Description

Intervention group 1: Midazolam, a dose of 0.3 mg per kg (maximum 15 mg), intramuscular, along with a placebo rectal gel tube, once when arrival to emergency department

Category

Treatment - Drugs

2

Description

Intervention group 2: Diazepam, a dose of 0.5 mg per kg (maximum 10 mg), rectal gel tube, along with intramuscular placebo, once when arrival to emergency department

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Emergency Department, Abuzar Hospital

Full name of responsible person

Saeid Sadeghian

Street address

Parastar (tohid) Street , Chaharshir, Abuzar Hospital, Ahvaz

City

Ahvaz

2

Recruitment center

Name of recruitment center

Pediatric Emergency Department, Golestan Hospital

Full name of responsible person

Saeid Sadeghian

Street address

Golestan Street, Golestan Hospital, Pediatric emergency department, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Behzad Sharif Makhmal Zadeh

Street address

Golestan street, Shahre Daneshgahi, Vice chancellor for research of Ahvaz University of Medical Sciences, Ahvaz

City

Ahvaz

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences, Medical School

Full name of responsible person

Saeid Sadeghian

Position

MD, Medical Intern

Other areas of specialty/work

Street address

Golestan street, Medical School, Ahvaz Jundishapur University of Medical Sciences, Ahvaz

City

Ahvaz

Postal code

6135715794

Phone

+98 61 3373 8573

Fax

+98 61 3333 7681

Email

s.saeid92@gmail.com; fmedicine@ajums.ac.ir

Web page address
<http://fmedicine.ajums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences,
Golestan Hospital

Full name of responsible person
Dr Reza Azizi Malamiri

Position
Professor of Pediatrics Neurology

Other areas of specialty/work

Street address
Golestan street, Department of Pediatrics, Golestan
Hospital, Ahvaz

City
Ahvaz

Postal code
3311861357

Phone
+98 61 3374 3063

Fax
+98 613743030

Email
Azizi.amin@gmail.com

Web page address
hgolestan.ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences,
Medical School

Full name of responsible person
Saeid Sadeghian

Position
MD, Medical Intern

Other areas of specialty/work

Street address
Golestan street, Medical School, Ahvaz Jundishapur
University of Medical Sciences, Ahvaz

City
Ahvaz

Postal code
6135715794

Phone
+98 61 3373 8573

Fax
+98 61 3333 7681

Email
s.saeid92@gmail.com

Web page address
<http://fmedicine.ajums.ac.ir>

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