

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Prophylactic treatment with oral diazepam to prevent recurrence of febrile seizures following triple vaccination with DTP and MMR: Randomize Controlled Trial

Protocol summary

Study aim

Prophylactic treatment with oral diazepam to prevent recurrence of febrile seizures following DTP and MMR vaccination: Randomized controlled trial

Design

This study is a double-blind clinical trial with parallel groups using randomized block method, and sampling is done by available method among patients with a history of febrile seizures following vaccine injection, in both intervention and control groups, and the sample size in each group was 30 patients.

Settings and conduct

This study will be performed on 60 patients with a history of febrile seizures following vaccination referred to Abuzar and Golestan hospitals in Ahvaz. The patients will be randomly divided into two groups based on a random table of computer generated numbers, and one group will receive oral diazepam and the other group will receive only diazepam anal rescue tube therapy and will not receive prophylactic treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 6 months to 6 years old who have had a seizure following vaccination and have no contraindications to vaccination. Patients with immunodeficiency, cancer, and patients taking corticosteroids are not included in the study. Exclusion criteria: Parental dissatisfaction, removal of the vaccine from the patient's vaccination schedule for any reason, history of oral diazepam allergy, Having contraindications for the MMR and DTP vaccines

Intervention groups

The intervention group in our study included individuals receiving oral diazepam. The control group received only salvage therapy with diazepam rectal tube.

Main outcome variables

The incidence of fever and also seizure at the time after the injection of the vaccines Occurrence of complications

such as drowsiness, dizziness, hypotension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210619051624N1**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Shahram Nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4228 5146

Email address

nasiri-sh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic treatment with oral diazepam to prevent recurrence of febrile seizures following triple vaccination with DTP and MMR: Randomize Controlled Trial

Public title

Treatment with Oral Diazepam for Prevention of Recurrence of Seizures following DTP and MMR Vaccination

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 6 months to 6 years old who have had a seizure following the vaccine There are no contraindications to vaccination. Patients with immunodeficiency, cancer, and patients taking corticosteroids are not included in the study.

Exclusion criteria:

Parental dissatisfaction Remove the vaccine from the patient's immunization schedule for any reason History of oral diazepam allergy Having contraindications for the MMR and DTP vaccines

Age

From **6 months** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, individuals are randomly divided into two groups based on four random block permutations. Also, in order to prevent confounding factors as well as reduce the bias caused by the opinions of the project guiding researchers, researchers involved in the levels of random sequencing, enrollment in terms of entry and exit criteria, assigning participants to the target groups will work separately.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this clinical trial, patients will be randomly divided into two groups based on a randomly generated table of computer-generated numbers, with one group receiving oral diazepam and the other group (control) receiving only life-saving diazepam anal tube therapy. And will not receive preventive treatment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Golestan Blvd., Golestan Town

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-12-29, 1399/10/09

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.037

Health conditions studied**1****Description of health condition studied**

Febrile seizures

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Numbers of seizure

Timepoint

After vaccination

Method of measurement

By asking parents of patients

2**Description**

Number of fevers

Timepoint

After vaccination

Method of measurement

By asking parents of patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group that will be treated with oral diazepam, and in addition to rectal Diazepam tube, Diazepam tablets are received from Sobhan Company at a dose of 1 mg per kg for the first 48 hours of the vaccine injection.

Category

Prevention

2

Description

Control group: The group that will only receive life-saving treatment with diazepam rectal tube in case of seizures lasting more than 2 to 5 minutes and will not receive preventive treatment.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Aboozar Children's Hospital

Full name of responsible person

Shahram Nasiri

Street address

Zeitoon Karmandi Ave

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1417561636

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+98 61 3444 9003

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karami.9926@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Ahvaz Jundishapur University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Kordnezhadian

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Shahram Nasiri

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only the results of the whole data are made available to the public

When the data will become available and for how long

Starting 9 months after publication

To whom data/document is available

Information is provided to Ahvaz University of Medical Sciences

Under which criteria data/document could be used

The use of data is merely intended to introduce the study and examine how the parameters are measured

From where data/document is obtainable

Dr. Shahram Nasiri (Project Manager)

What processes are involved for a request to access data/document

No use these data in another study

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Kordnezhadian

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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