

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Oral diazepam in febrile seizures following acellular pertussis vaccination

Protocol summary

Study aim

Evaluating the effect of oral diazepam on febrile seizures following pertussis vaccination

Design

Randomized clinical trials with control group, parallel group

Settings and conduct

The sampling is done in Emam Hossein Hospital, Isfahan. The intervention group is under treatment with diazepam tablet at a dose of 1 mg/kg daily as three times a day until 48 hours after vaccine injection and the control group is under treatment with rectal diazepam in initial of seizure with a dose of 0.5 mg/kg.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages more than one year and a history of febrile seizures. Exclusion criteria: Having contraindications for the pertussis vaccine, continuous usage of anticonvulsants in the child, and the parents' unwillingness to continue participation in this study.

Intervention groups

The intervention group: under treatment with diazepam tablet at a dose of 1 mg/kg daily as three times a day until 48 hours after vaccine injection. The control group: under treatment with rectal diazepam in initial of seizure with a dose of 0.5 mg/kg.

Main outcome variables

The incidence of fever and also seizure at the time after the injection of the pertussis vaccine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N24**

Registration date: **2018-11-02, 1397/08/11**

Registration timing: **retrospective**

Last update: **2018-11-02, 1397/08/11**

Update count: **0**

Registration date

2018-11-02, 1397/08/11

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-06-03, 1394/03/13

Expected recruitment end date

2017-12-30, 1396/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Oral diazepam in febrile seizures following acellular pertussis vaccination

Public title

Effect of diazepam on seizures following fever

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 1 year History of febrile seizures

Exclusion criteria:

Having contraindications for the pertussis vaccine,

including the occurrence of seizures following vaccine injecting Continuous usage of anticonvulsants in the child The parents' disinclination to continue participation in this study

Age

From **18 months** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are divided randomly into two intervention and control groups by random allocation software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2017-02-01, 1395/11/13

Ethics committee reference number

IR.MUI.REC.1396.6064

Health conditions studied

1

Description of health condition studied

Febrile convulsions

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Numbers of seizure and fever

Timepoint

Third and seventh days after the injection of the vaccine

Method of measurement

By asking parents of patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Under treatment with diazepam tablet at a dose of 1 mg/kg daily as TID until 48 hours after vaccine injection.

Category

Prevention

2

Description

Control group: Under treatment with rectal diazepam in the initial of seizure at a dose of 0.5 mg/kg

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Rose Soltani

Street address

Emam Khomeyni

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1435915371

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Sponsors / Funding sources

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr Rose Soltani

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of medical Sciences

Full name of responsible person

Ali Mehrabi Koushki

Position

Msc/ head of research department

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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 3 months after publication
To whom data/document is available
Information is provided to Isfahan 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. Rose Soltani (Project Manager) Address: Imam Hossein Hospital, Imam Khomeini St, Isfahan, Iran Tel: 00983136688597 Email: rosesoltani@gmail.com Mobile: 00989133023280
What processes are involved for a request to access data/document
1. No use these data in another study 2. Member of the Faculty of Medicine of Isfahan University of Medical Sciences 3. No data access to someone else
Comments