Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Country
Iran (Islamic Republic of)
Phone
+98 31 3629 1510
Email address
mehrabi@mui.ac.ir

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
Isfehan

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

City
Isfahan

Province
Isfehan

Postal code
1435915371

Phone
+98 31 3386 6266

Email
rosesoltani@gmail.com

Web page address
http://ehuch.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Dr mansoor siavash

Street address
Isfahan University of Medical Sciences, Hezar Jerib street

City
Isfahan

Province
Isfehan

Postal code
8565458525

Phone
+98 31 3668 8597

Email
keyvanghadimi@yahoo.com

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

Street address
Hezar Jarib

City
Isfahan

Province
Isfehan

Postal code
7346181746

Phone
+98 31 3668 8597

Email
rosesoltani@gmail.com

Person responsible for scientific 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

Street address
Hezar Jarib

City
Isfahan

Province
Isfehan

Postal code
7346181746

Phone
+31 36688597

Email
rosesoltani@gmail.com

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

Street address
research department, Alzahra hospital, Isfahan

City
isfahan

Province
Isfehan

Postal code
8434193474

Phone
+31 33563466

Fax
+98 31 3669 2174

Email
mehrabi@mui.ac.ir

Web page address

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