

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of side effects of cetirizine syrup in infants 3-6 months with urticaria and atopic dermatitis

Protocol summary

Study aim

Effects of Cetirizine Side effects of Cetirizine

Design

In this research, 30 eligible children patients with eczema and urticaria referring to allergist were chosen purposefully and a code was allocated to each one of them. Then, patients were serially go to study.

Investigate before and after treatment.

Settings and conduct

this study do in Boalisina hospital with not blinding

Participants/Inclusion and exclusion criteria

Children between 3 to 6 months with eczema and urticaria. not use other antihistamines. not other disorders.

Intervention groups

All of patients use Cetirizine with dose of 0.25mg/kg.

Main outcome variables

Side effects and effect of drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110531006660N8**

Registration date: **2020-03-31, 1399/01/12**

Registration timing: **retrospective**

Last update: **2020-03-31, 1399/01/12**

Update count: **0**

Registration date

2020-03-31, 1399/01/12

Registrant information

Name

Javad Ghafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3326 0054

Email address

ghafari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of side effects of cetirizine syrup in infants 3-6 months with urticaria and atopic dermatitis

Public title

use of cetirizine in infants 3-6 months

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

infants with 3-6 months age;urticaria;eczema

Exclusion criteria:

sleep apnea in infant or another siblings sensitivity to cetirizine use of other antihistamines QT interval more than 45 ms

Age

From **3 months** old to **6 months** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of pharmaceutical science research center

Street address

Pharmaceutical faculty, Darya Road

City

Sari

Province

Mazandaran

Postal code

48471-93696

Approval date

2018-06-04, 1397/03/14

Ethics committee reference number

1815

Health conditions studied

1

Description of health condition studied

Cetirizine

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Clinical resolution of urticaria and eczema

Timepoint

Before and after 10 days treatment

Method of measurement

Visit and ECG

Secondary outcomes

1

Description

side effects of drug

Timepoint

10 days

Method of measurement

Visit and ECG

Intervention groups

1

Description

All of patients use cetirizine (0.25 mg/kg/day) for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Boalisina Hospital

Full name of responsible person

Javad Ghaffari

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Pasdaran Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Reza Alizadeh-Navaei

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4815838477

Phone

+98 11 3325 7230

Email

Reza_nava@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Javad Ghaffari

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Allergy

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All of data shared except name`s of patients

When the data will become available and for how

long

After one month

To whom data/document is available

All of people

Under which criteria data/document could be used

No limitation

From where data/document is obtainable

By email

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

After application, data sent

Comments