

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of dexamethasone with prednisolone in controlling asthma attacks in children aged 2-10 years in pediatric clinics in Qom in 2018-19

Protocol summary

Study aim

Comparison of the effect of dexamethasone with prednisone in the treatment of acute asthma exacerbation

Design

Clinical trial with parallel groups, one-way blind, without randomization, on 100 patients.

Settings and conduct

This research was conducted by clinical trial in the office and clinic of Ayatollah Golpayegani Hospital in Qom in 2018 - 2019. In this study; out of the total number of patients with acute asthma attack, 100 eligible patients were selected and studied. The procedure was as follows: at first, patients with acute asthma were identified by a pediatrician according to GINA criteria after selecting the medication regimen and performing other measures; Parents were given the necessary explanations about the purpose of the research and if they wish and consent to participate in the research; Questionnaires were completed under the supervision of the researcher and with the necessary explanations. The researcher followed up by phone on the seventh day of treatment; she complete the questionnaire questions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 2 to 10 years old; definitive asthma according to GINA criteria; patients with refractory asthma according to GINA criteria. Exclusion criteria: having a medical condition that affects outcomes such as viral or bacterial infections of the airways; taking antibiotics in the last month; lack of compliance with medication; patient reluctance.

Intervention groups

In this clinical trial study, 100 patients with asthma were selected and divided into two groups. Both groups were approved for routine treatment with salbutamol and oxygen spray and For the first group, dexamethasone is prescribed in two doses of 0.6 mg / kg / dose and for the

second group, oral prednisone at a dose of 1.5 mg / kg / day is prescribed for 5 days.

Main outcome variables

Control of asthma attack with GINA and VAS criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201005048939N1**

Registration date: **2020-10-20, 1399/07/29**

Registration timing: **retrospective**

Last update: **2020-10-20, 1399/07/29**

Update count: **0**

Registration date

2020-10-20, 1399/07/29

Registrant information

Name

Hodasadat Safavisohi

Name of organization / entity

Islamic Azad University of Qom

Country

Iran (Islamic Republic of)

Phone

+98 25 3292 9647

Email address

h.sss.3.smiley@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-01-05, 1397/10/15

Trial completion date

2019-01-12, 1397/10/22

Scientific title

Comparison of the effect of dexamethasone with prednisolone in controlling asthma attacks in children aged 2-10 years in pediatric clinics in Qom in 2018-19

Public title

Comparison of the effect of dexamethasone with prednisolone in controlling asthma attacks

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 2 to 10 years old Definitive asthma according to GINA criteria Patients with refractory asthma according to GINA criteria

Exclusion criteria:

Having a medical condition that affects outcomes such as viral or bacterial infections of the airways Taking antibiotics in the last month Lack of compliance with medication Patient reluctance

Age

From **2 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

The study samples were children and their parents did not know about the medication regimen chosen by the doctor

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of the Faculty of Pharmacy and Pharmaceutical Sciences, Islamic Azad University of

Street address

Khaghani St., Shariati St.

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.IAU.PS.REC.1399.052

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

Asthma

ICD-10 code

J45.4

ICD-10 code description

Moderate persistent asthma with status asthmaticus

Primary outcomes**1****Description**

Control asthma attack

Timepoint

At the beginning of the study and day 7 after starting treatment

Method of measurement

Visual Analogue Scale, Global Initiative for Asthma

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in this group were treated with dexamethasone at a dose of 0.6 mg / kg (max = 16 mg / dose) with intramuscular method for two days. Salbutamol and oxygen sprays were performed for all patients at the time of referral.

Category

Treatment - Drugs

2**Description**

Control group: Patients in this group underwent oral prednisolone at a dose of 1.5 mg / kg / day (max = 60 mg / day) for 5 days. Salbutamol and oxygen sprays were performed for all patients at the time of referral.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Clinic of Ayatollah Golpayegani Hospital,
Qom

Full name of responsible person

Hoda Safavi

Street address

Motahhari Square, Rahbar Street

City

Qom

Province

Ghoum

Postal code

3714963744

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+98 25 3616 1111

Email

h.golpayegani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Qolam Reaza Najafi

Street address

Pardisan, University Blvd.

City

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Postal code

3749113191

Phone

+98 25 3280 8080

Email

q_najafi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mohmad Javad Qasem zade

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Islamic Azad University, next to Social Security
Insurance, 15 Khordad Blvd., Shah Seyed Ali Square

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qasemzade.m@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hoda Sadat Safavid

Position

physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hoda Sadat Safavid

Position

physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

Information on the main outcome

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

For researchers working in academic and scientific
institutions

Under which criteria data/document could be used

Use to insert in the article with reference

From where data/document is obtainable

Islamic Azad University of Qom

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

By inserting the request in the email and replying after
viewing the email

Comments