Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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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Province

Ghoum

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3749113191

Phone

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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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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