

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of dexamethasone and dexamethasone with nebulised L-epinephrine in treatment of croup.

Protocol summary

Summary

In this clinical trial study, patients with moderate to severe croup will be enrolled in two groups with intramuscular Dexamethasone and normal saline nebulizer or intramuscular Dexamethasone (at a single dose of 0.6mg/kg) and nebulized epinephrine (0.5mL of 1:1000 (1mg/ml) in 3ml Normal saline solution for less than 10kg weight and 1mL for more than 10kg weight. In control group, 3ml Normal saline solution will be nebulized. Before treatment and 30 and 60 minutes after treatment, croup score and respiratory rate per minute will be calculated for each patient and age, gender, duration of stay in the emergency ward and hospitalization status will be recorded. Croup diagnosis will be based on clinical signs and croup scoring according to asthma and allergy specialist's scoring.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105264396N2**

Registration date: **2011-06-13, 1390/03/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-13, 1390/03/23

Registrant information

Name

Iraj Mohammadzadeh

Name of organization / entity

Non-communicable pediatric diseases research center

Country

Iran (Islamic Republic of)

Phone

+98 11 1324 2151

Email address

i.mohammadzadeh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University Of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-08-23, 1390/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dexamethasone and dexamethasone with nebulised L-epinephrine in treatment of croup.

Public title

The effect of dexamethasone and dexamethasone with nebulised L-epinephrine in treatment of croup.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: children aged 6months to 6years old suffering from croup. Exclusion criteria: receiving steroid during last month, asthma, pneumonia, congenital heart diseases.

Age

To **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 94

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Babol, Ganjafruz Street

City

Babol

Postal code

4731741151

Approval date

2010-02-28, 1388/12/09

Ethics committee reference number

3150

Health conditions studied

1

Description of health condition studied

Croup

ICD-10 code

J05.0

ICD-10 code description

Acute obstructive laryngitis [croup]

Primary outcomes

1

Description

Croup Score

Timepoint

Before treatment, 30min after treatment and 1 hour after treatment

Method of measurement

Number(0-6)

Secondary outcomes

1

Description

Hospitalization, Duration of stay in emergency, Respiratory Rate

Timepoint

nothing

Method of measurement

Yes/No, Hour, Number

Intervention groups

1

Description

In this study, control group, will be treated with 0.6mg/kg intramuscular Dexamethasone at a single dose and 3cc nebulized N/S. Before treatment and 30 and 60 minutes after treatment, croup score and respiratory rate per minute will be calculated for each patient and age, gender, duration of stay in the emergency ward and hospitalization status will be recorded. Croup diagnosis will be based on clinical signs and croup scoring according to asthma and allergy specialist's scoring.

Category

Treatment - Drugs

2

Description

In this study, the case group will be treated with 0.6mg/kg intramuscular Dexamethasone at a single dose and nebulized epinephrine (0.5mL of 1:1000 (1mg/mL) in 3mL N/S for less than 10kg weight and 1mL for more than 10kg weight. Before treatment and 30 and 60 minutes after treatment, croup score and respiratory rate per minute will be calculated for each patient and age, gender, duration of stay in the emergency ward and hospitalization status will be recorded. Croup diagnosis will be based on clinical signs and croup scoring according to asthma and allergy specialist's scoring.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amircola Pediatrics Hospital

Full name of responsible person

Iraj Mohammadzadeh M.D. Children Subspecialist of Allergy and Immunology

Street address

Babol, Amirkola Children's Hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Amrollah Mostafazadeh

Street address

Babol university of medical sciences

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Amirkola Children's Hospital

Full name of responsible person

Iraj Mohammadzadeh M.D

Position

Subspecialist in Children's Allergy and Immunology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty