Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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 Siences

Street address

Babol,Ganjafrooz 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

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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
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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
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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