

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Nebulized Epinephrin in the Treatment of Patient's Croup

Protocol summary

Summary

Hypothesis is that there is no difference between Croup's Scorings and discharge's times of patients who will get "Nebulized Epinephrine+ Dexamethason" compare with whom they will get only ordinary care including "Cool Nebulized normal saline+ Dexamethason" . We will divide patients into two groups randomly, intervention and control. First we will measure all of patients for Croup Scoring, Blood pressure, Heart rate and Respiratory rate before treatment. Intervention Group: This patients will be treated by Epinephrine (0.5 mg / kg, max dose: 5 mg) nebulized + Dexamethasone(0.6 mg / kg, max dose: 8 mg) and we will measure again Croup scoring (Westley Score), Blood pressure, Heart rate and Respiratory rate on the minutes time of 30, 60, 90 and 120. Control group: This patients will get only Dexamethasone (0.6 mg / kg, max dose: 8 mg) + Cool nebulized normal saline. We will measure again Croup Scoring, Blood pressure, Heart rate and Respiratory rate on the minutes of 30, 60, 90 and 120 as well.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105156491N1**

Registration date: **2011-12-03, 1390/09/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-03, 1390/09/12

Registrant information

Name

Ali Sabbagh

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nebulized Epinephrin in the Treatment of Patient's Croup

Public title

Effect of Nebulized L-Epinephrin in the Treatment of Patient's Croup

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: All of patients aged between 6 months and 6 years. Exclusion Criteria: patients who are known case of cardiovascular disease; patients whose parents refuse to participate.

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 174

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

Ethics Committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Pardis Site, Sardasht, Beseij square, PO Box (1884)

City

Arak

Postal code

3848176941

Approval date

2011-04-20, 1390/01/31

Ethics committee reference number

5-106-90

Health conditions studied

1

Description of health condition studied

Croup

ICD-10 code

J05.0

ICD-10 code description

J05.0 Acute obstructive laryngitis [croup]

Primary outcomes

1

Description

Croup score

Timepoint

the minutes of 30, 60, 90 and 120 after treatment.

Method of measurement

Westley Score

Secondary outcomes

1

Description

Blood pressure

Timepoint

the minutes of 30, 60, 90 and 120 after treatment.

Method of measurement

physical exam

2

Description

Heart rate

Timepoint

the minutes of 30, 60, 90 and 120 after treatment.

Method of measurement

physical exam

3

Description

Respiratory rate

Timepoint

the minutes of 30, 60, 90 and 120 after treatment.

Method of measurement

physical exam

Intervention groups

1

Description

Intervention: Epinephrine (0.5 mg / kg, max dose: 5 mg) plus normal saline (10 cc) which this cocktail will be nebulized for 20 minutes (it is repeatable for 3 times). Also, these patients will receive Dexamethasone (0.6 mg / kg/IM, max dose: 8 mg) while infant or child sits on the mother's arm.

Category

Treatment - Drugs

2

Description

control: nebulized normal saline (it is repeatable for 3 times) associated with Dexamethasone (0.6 mg / kg, max dose: 8 mg) while infant or child sits on the mother's arm.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Aziz Eghbali, Ali Sabbagh

Street address
Amir'Kabir Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
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Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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

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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