Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of intramuscular injection of a single dose of dexamethasone in infants under 2 years suffering acute bronchiolitis

Protocol summary

Summary

Objectives: Evaluation of the effect of intramuscular injection of a single dose of dexamethasone in infants under 2 years suffering acute bronchiolitis, Design: Study is a randomized double blind clinical trial, Setting and conduct: 80 Infant children under 2 years of age are admitted to the hospital Mohammad Kermanshahi and acute bronchiolitis by specialist physicians diagnosed. If no exclusion criteria were randomly divided into 2 groups, drug and placebo. Participants: Infants less than 2 years old؛ The first episode of wheezing with respiratory distress observed, Upper respiratory tract have infection,) Intervention: In the drug group (1 mg / kg) intramuscular dexamethasone and placebo groups are equally placebo injection, main outcome measures: RDAI scored arrival time, 4 hours and 7 days after injection in both groups are measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120218974N2**
Registration date: **2015-03-02, 1393/12/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-02, 1393/12/11

Registrant information

Name

Simin Gheini

Name of organization / entity

Kermanshah University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Siences, Adress: Vice chancellor for research, Building No. 2 of Kermanshah University of Medical Sciences, Shahidbeheshti Bolvar, Kermanshah.

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of intramuscular injection of a single dose of dexamethasone in infants under 2 years suffering acute bronchiolitis

Public title

The effect of dexamethasone injection in infants with acute bronchiolitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Infants less than 2 years old؛ The first episode of wheezing with respiratory distress observed؛ Upper respiratory tract have infection. Exclusion criteria: Infants who have a history of wheezing or bronchodilator therapy؛ Prematurity؛ Neonatal ventilation؛ disease of chronic Heart and lung؛ Aspiration؛ Problems nerve / muscle؛ immunocompromised؛ Tachycardia greater than

180 beats per minute؛ respiratory rate of 100 per minute or previous use of glucocorticoid.

Age
From **1 day** old to **2 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kermanshah University of Medical Sciences Ethics Committee

Street address
Kermanshah University of Medical Sciences; Shahid Beheshti Bolvar; Kermanshah

City
Kermanshah

Postal code

Approval date
2014-01-14, 1392/10/24

Ethics committee reference number
51694

Health conditions studied

1

Description of health condition studied
Acute bronchiolitis

ICD-10 code
J20.9

ICD-10 code description
Acute bronchitis, unspecified

Primary outcomes

1

Description
RADI Score

Timepoint
Arrival time, After 4 hours and 7 day later

Method of measurement
According to the criteria of Respiratory Disease Assessment Instrument

Secondary outcomes

empty

Intervention groups

1

Description
Dexamethasone intramuscularly amount (1 mg / kg body weight)

Category
Placebo

2

Description
placebo intramuscularly amount (1 mg / kg body weight)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mohammad Kermanshahi Hospital

Full name of responsible person
Sareh Farshadfar

Street address
Infant Group, Mohammad Kermanshahi Hospital, HelalAhmar Avenue, Kermanshah

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person
Farid Najafi

Street address
Vice chancellor for research, Building No. 2 of Kermanshah University of Medical Sciences, Shahidbeheshti Bolvar

City
Kermanshah

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kermanshah 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

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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