

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

###### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3721 8202

##### Email address

s.gheini@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences, Address: 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

**Contact**  
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Kermanshah university of medical sciences  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*