

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Randomized clinical trial of comparing oral and inhalant corticosteroids in treatment of mild to moderate attack of asthma in children

#### Protocol summary

##### Summary

(1) Objectives: Our aim in this is to compare effects of oral and inhalant corticosteroids in treatment of mild to moderate attack of asthma in children. (2) Design: This a randomized not blinded clinical trail. Study population are 60 children between 5 to 14 years old referring to Children Hospital emergency with mild to moderate asthma attack. These children will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent. For randomizing the patients we will use Excel software (computerized randomization). (3) Setting and conduct: Patients will be randomly divided into two groups of receiving Salbutamol spray plus oral prednisolon and receiving Salbutamol spray plus Budesonide spray. Patients will be visited in first (acute attack), third and seventh day (end of treatment) of treatment and clinical examination, spirometry and pixelometry will be performed. Severity of asthma will be defined in all the visits. Inclusion criteria are having mild to moderate asthma attack and age between 5 to 14 years old. Exclusion criteria are unwillingness to participate in the study. (4) Intervention: First group will be treated with Salbutamol spray (2 puffs every four hours for 48 hours, each puff contains 100 micro grams of the drug) plus oral prednisolon (2 milligrams per each kilograms of body weight for one week). Second group will be treated with Salbutamol spray (2 puffs every four hours for 48 hours, each puff contains 100 micro grams of the drug) plus Budesonide spray (2 puffs every 12 hours, for one week, each puff contains 200 milligrams of the drug). (5) Main outcome measures: Spirometry (FEV1, FEV1/FVC, FEF %25-%75) and pixelometry criteria will be evaluated on first and seventh day and diurnal and nocturnal symptoms will be evaluated on first, third and seventh day of study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013101214988N1**

Registration date: **2013-11-05, 1392/08/14**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-11-05, 1392/08/14

##### Registrant information

###### Name

Mohammad Barzegar

###### Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3526 2265

###### Email address

phrc\_mb@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-07-11, 1392/04/20

##### Expected recruitment end date

2014-01-10, 1392/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Randomized clinical trial of comparing oral and inhalant corticosteroids in treatment of mild to moderate attack of asthma in children

**Public title**

Comparison of two kind of drugs in the treatment of asthma

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Having mild to moderate asthma attack; Age between 5 to 14 years old. Exclusion criteria: Unwillingness to participate in the study.

**Age**

From **5 years** old to **14 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not 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 Tabriz University of Medical Sciences

**Street address**

Ethics committee, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

**City**

Tabriz

**Postal code****Approval date**

2013-06-08, 1392/03/18

**Ethics committee reference number**

5/4/2240

**Health conditions studied****1****Description of health condition studied**

Asthma

**ICD-10 code**

J45

**ICD-10 code description**

Asthma

**Primary outcomes****1****Description**

Forced expiratory volume in the first second

**Timepoint**

In the first and seventh day of the study

**Method of measurement**

By using spirometry device

**2****Description**

FEV1/FVC

**Timepoint**

In the first and seventh day of the study

**Method of measurement**

By using spirometry device

**3****Description**

Diurnal symptoms of the disease

**Timepoint**

In the first, third and seventh day of the study

**Method of measurement**

By examiner

**4****Description**

Nocturnal symptoms of the disease

**Timepoint**

In the first, third and seventh day of the study

**Method of measurement**

By examiner

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First group will be treated with Salbutamol spray (2 puffs every four hours for 48 hours, each puff contains 100 micro grams of the drug) plus oral prednisolon (2 milligrams per each kilograms of body weight for one week).

**Category**

Treatment - Drugs

## 2

### Description

Second group will be treated with Salbutamol spray (2 puffs every four hours for 48 hours, each puff contains 100 micro grams of the drug) plus Budesonide spray (2 puffs every 12 hours, for one week, each puff contains 200 milligrams of the drug)

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Tabriz Children Hospital

**Full name of responsible person**

Dr. Masoumeh Ghasempour

**Street address**

Tabriz Children Hospital, Sheshgelan Street, Farmanfarmayan Street, Tabriz

**City**

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Seyyed Kazem Shakouri

**Street address**

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square, Tabriz

**City**

Tabriz

**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, Tabriz 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**

Tabriz Children Hospital

**Full name of responsible person**

Dr. Masoumeh Ghasempour

**Position**

Pediatric diseases resident

**Other areas of specialty/work****Street address**

Department of Pediatric diseases, Tabriz Children Hospital, Sheshgelan Street, Farmanfarmayan Street, Tabriz

**City**

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**Postal code****Phone**

+98 41 1526 2255

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masoumeh\_gh\_a@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz Children Hospital

**Full name of responsible person**

Dr. Nemat Bilan

**Position**

Professor of pediatric lung diseases

**Other areas of specialty/work****Street address**

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Bilan@tbzmed.ac.ir

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz Children Hospital

**Full name of responsible person**

Dr. Masoumeh Ghasempour

**Position**

Pediatric diseases resident

**Other areas of specialty/work****Street address**

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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*