# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Compare of Forced Expiratory Volume in 1 second (FEV1) and FEV1/Forced Vital Capacity(FVC) after use fluticasone/salmeterol in the form of Metered-dose Injaler (MDI) and Dry Powder Inhaler( DPI) for the treatment of children's asthma.

## Protocol summary

**Study aim**

Comparison of Forced Expiratory Volume in 1 second (FEV1),/Forced Vital Capacity (FVC) , FEV1/FVC , Forced Expiratory Flow (FEF) in two groups treated with combination fluticasone/salmeterol in the form of Metered Dose Inhaler (MDI) with form of Dry Powder Inhaler ( DPI) in asthma in children.

**Design**

86 children over six years old with moderate asthma who required combined ICS/LABA treatment. These children were referred to the Masih Daneshvari Hospital clinic and were randomly divided into two equal groups. One group received treatment via MDI, while the other group used DPI inhalation.

**Settings and conduct**

The firs in Masih daneshvari hospital, spirometry was performed for all participants. After one month of treatment, a follow-up spirometry was conducted. The treatment groups were then switched: those initially using MDI were switched to DPI, and vice versa. Spirometry was repeated one month after the switch, and the results were analyzed and compared.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria - Children over 6 years old with moderate asthma need combined treatment with ICS/LABA. -stable condition -parent consent Exclusion criteria - Patients with emergency conditions such as asthma exacerbation

**Intervention groups**

The group using fluticasone/salmeterol combination in MDI form. The group using fluticasone/salmeterol combination in DPI form.

**Main outcome variables**

Lung Volumes Symptoms Drug Side Effect

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220812055665N2**
Registration date: **2025-10-07, 1404/07/15**
Registration timing: **retrospective**

Last update: **2025-10-07, 1404/07/15**
Update count: **0**

**Registration date**

2025-10-07, 1404/07/15

**Registrant information**

**Name**

Zohre Akbari jokar

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 3623 9056

**Email address**

zohreakbari2351@yahoo.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-04-21, 1402/02/01

**Expected recruitment end date**

2024-03-20, 1403/01/01

**Actual recruitment start date**

2023-04-21, 1402/02/01

**Actual recruitment end date**

2024-03-20, 1403/01/01

**Trial completion date**

2024-04-20, 1403/02/01

**Scientific title**
Compare of Forced Expiratory Volume in 1 second (FEV1) and FEV1/Forced Vital Capacity(FVC) after use fluticasone/salmeterol in the form of Metered-dose Injaler (MDI) and Dry Powder Inhaler( DPI) for the treatment of children's asthma.

**Public title**
Compare of FEV1 and FEV1/FVC after use fluticasone/salmeterol in the form of MDI and DPI for the treatment of children's asthma

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Children over 6 years with moderate asthma requiring therapy with ICS/LABA stable condition Parental consent
**Exclusion criteria:**
Unstable condition

**Age**
From **6 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **86**
Actual sample size reached: **86**

**Randomization (investigator's opinion)**
Not randomized

**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 Medical University of Shahid Beheshti
**Street address**
No 15, Salmasi, South Mofatteh ,Haft Tir Square
**City**
Tehran
**Province**
Tehran
**Postal code**
1573633916
**Approval date**
2023-05-22, 1402/03/01
**Ethics committee reference number**
IR.SBMU.MSP.REC.1402.232

## Health conditions studied

### 1

**Description of health condition studied**
asthma
**ICD-10 code**
J45.9
**ICD-10 code description**
Other and unspecified asthma

## Primary outcomes

### 1

**Description**
Forced Expiratory Volume in 1 second (FEV1)
**Timepoint**
beginning of the study , One month after starting teatment , One month after starting treatment
**Method of measurement**
Spirometry

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: In this group, the combination of fluticasone/salmeterol inhaler in the form of MDI is used every 12 hours at the dose required by the patient for one month, in the second month, the combination of fluticasone/salmeterol inhaler in the form of DPI is prescribed to the patient every 12 hours. The dose used varies based on each patient. On average, a dose of 25/125 is used.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: In this group, the combination of fluticasone/salmeterol inhaler in the form of DPI is used every 12 hours at the dose required by the patient for one month, in the second month, the combination of fluticasone/salmeterol inhaler in the form of MDI is prescribed to the patient every 12 hours. The dose used varies based on each patient.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Masih Daneshvari Hospital
**Full name of responsible person**
Zohre Akbari Jokar
**Street address**
darabad
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Zohreakbari2351@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
zohre akbari jokar
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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**
Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**
1

**Public or private sector**
Private

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Other

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Zohre Akbari Jokar
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
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No.15, Salmasi , South Mofateh , 7th Tir Square, Tehran
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Other areas of specialty/work**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available