

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The comparison between Beclomethason Dipropionate and Fluticasone Propionate in 6-17 year old patients with moderate asthma

Protocol summary

Summary

The aim of study is to compare the effectiveness of Beclomethason Dipropionate (BDP) and Fluticasone Propionate (FP) in 6-17 year old patients with moderate asthma. Fifty patients aged between 6-16 years referred to allergy clinic of Valie Asr hospital between December and September with symptoms of moderate asthma within at least 6 months were selected. Patients with other known causes of wheezing such as cystic fibrosis and heart disorders were excluded from the study. None of the patients had been receiving inhaled corticosteroids prior the study. The patients randomly allocated into two groups. The first group received 250 µg FP twice daily and the second group received 200 µg BDP TDS for 3 months and pulmonary function tests were done at the beginning of study and at monthly intervals. Daily and night symptoms and continuation of drug prescription were assessed monthly. Both ICS were registered trade mark of Cipla Company and prescribed open label. Pulmonary function tests were done by one person who did not know any information about the kind of therapy. The study protocol was approved by the ethic committee of Zanzan University of Medical Science and all patients or their parents gave written informed consent. Comparisons between two groups were made by Mann-Whitney test and chi-Squared test. P value more than 0.05 was accepted as statistically significant. The outcome of study was improvement of daily and night symptoms, PFT results and reduction in rescue medication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812042976N2**

Registration date: **2010-05-02, 1389/02/12**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2010-05-02, 1389/02/12

Registrant information

Name

Akefeh Ahmadiashar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 1422 3095

Email address

akefeh45@zums.ac.ir

Recruitment status

Not enough for processing

Funding source

Zanzan University of Medical Science

Expected recruitment start date

2007-12-07, 1386/09/16

Expected recruitment end date

2007-07-07, 1386/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between Beclomethason Dipropionate and Fluticasone Propionate in 6-17 year old patients with moderate asthma

Public title

The comparison between Beclomethason Dipropionate and Fluticasone Propionate in 6-16 year old patients with moderate asthma

Purpose

Treatment

Inclusion/Exclusion criteria
 Patients with symptoms of cough and wheezing at night and after exercise and FEV1 between 60-80% were included in the study. Patients with other known causes of wheezing such as cystic fibrosis and heart disorders were excluded from entry into study. None of patients had been receiving inhaled corticosteroids prior the study.

Age
 From **6 years** old to **16 years** old

Gender
 Both

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **50**

Randomization (investigator's opinion)
 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

Ethic Commity of Zanjan University of Medical Science

Street address

Zanjan University of Medical Science

City

Zanjan

Postal code

45139-56183

Approval date

2007-12-07, 1386/09/16

Ethics committee reference number

11/3-3/4450

Health conditions studied

1

Description of health condition studied

Effects of inhaled corticosteroids (ICS) in moderate asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Improvement of daily symptoms

Timepoint

weekly

Method of measurement

questionare

2

Description

improvement of night symptoms

Timepoint

monthly

Method of measurement

questionare

3

Description

reduction of rescue medication

Timepoint

monthly

Method of measurement

questionare

Secondary outcomes

1

Description

improvement of PFT

Timepoint

monthly

Method of measurement

spirometeric measurement

Intervention groups

1

Description

6-16 yrs old pations with moderate asthma

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valie Asr hospital Allergy clinic

Full name of responsible person
Akefeh Ahmadi Afshar
Street address
Gavazang road, Mousavi Hospital
City
Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University Of Medical Science
Full name of responsible person
AKEFEH AHMADI AFSHAR
Street address
Gavazng Road, Mousavi Hosp
City
Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University Of Medical Science
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
Beheshti Hospital
Full name of responsible person
Mogimi Haji Mohsen
Position
Pediatrician
Other areas of specialty/work
Street address
Beheshti Hospital
City
Langrood
Postal code
Phone
+98 24 1413 0000
Fax
Email
moghimim m@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
ZANJAN UNIVERSITY OF MEDICAL SCIENCE
Full name of responsible person
Akefeh Ahmadi Afshar
Position
Assistant prof, Subspecialist of immunology and allergy
Other areas of specialty/work
Street address
GAVASNG ROAD , MOUSAVI HOSP
City
Zanjan
Postal code
45139-56183
Phone
+98 24 1422 3095
Fax
+98 24 1413 1340
Email
akefeh45@zums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Science
Full name of responsible person
AKefeh AhmadiAfshar
Position
Assistant prof
Other areas of specialty/work
Street address
Gavazang Avenu Valie Asr Hospital
City
Zanjan
Postal code
45139-56183
Phone
+98 24 1422 3095
Fax
Email
akefeh45@zums.ac.ir
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