Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparison between ciclesonide and fluticasone in patients with mild persistant asthma asthma

Protocol summary

Summary

A randomized, multicenter trial. Inclusion criteria: Ladies and gentlemen between 15 and 65 years as the definitive diagnosis of asthma is confirmed as mild persistent asthma. Exclusion criteria: A) Having any of the criteria for moderate persistent asthma B) Pregnancy - Breastfeeding C) sensitivity to corticosteroids D) other lung diseases like COPD E) use of systemic corticosteroids in acute asthma attacks during two months before the run in period. Sample size:356 patients. Spirometric parameters, including FEV1 and FVC will be used. To assess patients' quality of life miniAQLQ questioner will be used. Primary efficacy variables includes changes in FEV1 over the course of treatment is compared with the initial spirometry. Secondary efficacy variables include changes in FVC, PEF, asthma attacks and changes in AQLQ total score. Eligible patients randomly will be assigned to receive fluticasone 100 twice daily with spacer via inhalation or ciclesonide 80 once daily with spacer via inhalation.The patients will be educated in order to true spacer use.The patients never receive any other drugs related to asthma except salbutamol as rescue medication

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201028597N1**
Registration date: **2012-04-03, 1391/01/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-03, 1391/01/15

Registrant information

Name
Seyed Mohammad Reza Hashemian
Name of organization / entity
NRITLD
Country
Iran (Islamic Republic of)
Phone
+98 21 2296 7767
Email address
smrhashemian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Massih Daneshvari Hospital

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between ciclesonide and fluticasone in patients with mild persistant asthma asthma

Public title

Ciclesonide comparison with fluticasone in mild persistent asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Ladies and gentlemen between 12 and 75 years as the definitive diagnosis of asthma is confirmed as mild persistent asthma: (Symptoms more than two days per week but less than daily incidence, symptoms at night more than two nights in month but

less thatn every night, FEV1 ≥ 80% predicted, FEV1 Variability% 20 -% 30 and the use of B2 agonists short acting more than two days a week but less than daily). Exclusion criteria: A) Having any of the criteria for moderate persistent asthma B) Pregnancy - Breastfeeding C) sensitivity to corticosteroids D) other lung diseases like COPD E) use of systemic corticosteroids in acute asthma attacks during two months before the run in period

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **356**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
National ethics committee in medical researches

Street address
Enghelab Ave reasearch and technology branch of ministry of health

City
Tehran

Postal code

Approval date
2011-11-19, 1390/08/28

Ethics committee reference number
49/1-ک90پ

Health conditions studied

1

Description of health condition studied
Asthma

ICD-10 code
J45.9

ICD-10 code description
Asthma, unspecified

Primary outcomes

1

Description
Forced expiratory volume in first second(FEV1)

Timepoint
Before intervention and then 2,4, 8, 16 and 24 weeks after start of intervention

Method of measurement
Spirometry

Secondary outcomes

1

Description
Forced vital capacity(FVC)

Timepoint
Before intervention and at 2, 4, 8, 16 and 24 th week and in any time that the patient was referred due to adverse events.

Method of measurement
Spirometry

2

Description
Number of asthma attacks

Timepoint
Any time it happened

Method of measurement
Recorded by patent himself/herself

3

Description
Total score of mini AQLQ questionare

Timepoint
Before intervention and at 2, 4, 8, 16 and 24 th week and in any time that the patient was referred due to adverse events.

Method of measurement
Questionare will be completed by patients

4

Description
Nasopharyngitis as an adverse event

Timepoint
Before intervention and at 2, 4, 8, 16 and 24 th week and in any time that the patient was referred due to adverse events.

Method of measurement
Physical examination and laboratory investigations if needed

5

Description
Any adverse effect due to drug consumption
Timepoint
Before intervention and at 2, 4, 8,16 and 24 th week and in any time that the patient was referred due to adverse events.
Method of measurement
Physical examination and laboratory investigations if needed

Intervention groups

1

Description
Eligible patients are randomly divided to two groups and the intervention group patients will be assigned to receive ciclesonide 80mg once daily with spacer via inhalation. These patients will be educated in order to true spacer use. The patients never receive any other drugs related to asthma except salbutamol as rescue medication.
Category
Treatment - Drugs

2

Description
Eligible patients are randomly divided to two groups and the control group patients will be assigned to receive fluticasone 100 mg twice daily with spacer via inhalation. These patients will be educated in order to true spacer use. The patients never receive any other drugs related to asthma except salbutamol as rescue medication.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Massih Daneshvari Hospital
Full name of responsible person
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Shahid Modarres Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Massih Daneshvari hospital
Full name of responsible person
Dr. Mohammadreza Masjedi
Street address
Daraabad-massih daneshvari hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Massih Daneshvari hospital
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Massih Daneshvari Hospital
Full name of responsible person
Dr Seied Alireza Mahdaviani
Position
Clinical allergy and immunology fellowship
Other areas of specialty/work
Street address
Daraabd
City
Tehran
Postal code
Phone
+98 21 2610 9930
Fax
Email
arishah65@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Massih Daneshvari Hospital

Full name of responsible person
Dr. Fanak Fahimi

Position
researcher of national research center of tuberculosis and lung diseases

Other areas of specialty/work

Street address
Daaraabd-massih daneshvari hospital

City
tehran

Postal code
1956944413

Phone
+98 21 2208 5855

Fax
+98 21 2208 5855

Email
arvin.najafi@gmail.com

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