

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison between ciclesonide and fluticasone in patients with mild persistent 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 persistent 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 than every night, FEV1 \geq 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 research and technology branch of ministry of health

City

Tehran

Postal code

Approval date

2011-11-19, 1390/08/28

Ethics committee reference number

49/1-۹۰پ

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 patient himself/herself

3

Description

Total score of mini AQLQ questionnaire

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 Mahdavian

Position

Clinical allergy and immunology fellowship

Other areas of specialty/work

Street address

Daraabd

City

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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

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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