

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of the efficacy and safety of Salmeflo and Seretide in patients with asthma

Protocol summary

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Summary

Title: Comparison of the efficacy and safety of Salmeflo and Seretide in patients with asthma, Objectives: Review clinical efficacy, adverse effects and patients satisfaction of Salmeflo compared to Seretide, Design: Controlled clinical trial, Blinding: Single blind , Inclusion criteria: Patients aged 18 years and older who are willing to participate and sign a consent form; Patients who have the ability of using the inhaler with correct technique; exclusion criteria: Using of Inhaled Corticosteroid or Long Acting Beta Agonist in the last month before entering the study; patients with known hypersensitivity to Beta 2 agonist or Inhaled Corticosteroid.

Recruitment status

Recruitment complete

Funding source

Sadaf Darou Saba Company

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014083014727N5**

Registration date: **2014-12-23, 1393/10/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-23, 1393/10/02

Registrant information

Name

Fanak Fahimi

Name of organization / entity

Shahid Behesti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8805 0939

Email address

Scientific title

Comparison of the efficacy and safety of Salmeflo and Seretide in patients with asthma

Public title

Clinical safety and efficacy study in asthmatic patients who use Salmeflo Inhaler

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 18 years and older who are willing to participate and sign a consent form; Patients who have the ability of using the inhaler with correct technique; exclusion criteria: Using of Inhaled Corticosteroid or Long Acting Beta Agonist in the last month before entering the study; patients with known hypersensitivity to Beta 2 agonist or Inhaled Corticosteroid; patients with lower respiratory system's infection (abnormal chest X ray) during the study; Alcoholics, drugs abuser; Patients who are pregnant or breastfeeding; Patients who use drug for another asthma trial; Patients with another severe and uncontrolled chronic disease, such as Heart failure, FC III, IV and history of myocardial infarction; Patients who show

symptoms of acute reactions during the study; Non-compliance patient with treatment protocols; Requiring to use oxygen or systemic corticosteroid during the study; Disability to record the use of rescue medication accurately.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Use the table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Behesti University of Medical Sciences

Street address

Next to Taleghani Hospital, A'rabi St., Yaman St., Chamran highway

City

Tehran

Postal code

Approval date

2014-09-14, 1393/06/23

Ethics committee reference number

0308/10827

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45 , J46

ICD-10 code description

Asthma , Status asthmaticus

Primary outcomes

1

Description

Comparison of averages of FEV1

Timepoint

Before study, Every 4 weeks after study

Method of measurement

by Spirometry

2

Description

comparison of disease management

Timepoint

Before Study, Every 4 weeks after study

Method of measurement

ACT query

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Salmeflo 125/25 , 2 puffs BID

Category

Treatment - Drugs

2

Description

Control group: Seretide 125/25, 2 puffs BID

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Dr Jalal Heshmat Nia

Street address

Shahid beheshti Street , Valiasr street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sadaf Darou Saba Company

Full name of responsible person

Niloofar Shamsolketabi

Street address

No 19, Tirdad Alley, Aliakbari St., Motahari St.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sadaf Darou Saba Company

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

Sadaf Darou Saba Company

Full name of responsible person

Dr. Ronak Saadati

Position

PhD in pharmaceuticals, Responsible pharmacist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Behesti University of Medical Sciences

Full name of responsible person

Dr. Fanak Fahimi

Position

Ph.D in clinical pharmacy

Other areas of specialty/work

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Niayesh-Valiasr crossing, Faculty of pharmacy

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Fax

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fahimi@sbmu.ir.ac

Web page address

Person responsible for updating data

Contact

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