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

Summary

Title: Comparison of the efficacy and safety of Salmeflo and Seretide in patients with asthma, Objectives: Review clinical efficacy, adverse effects and patients satisfacation 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.

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

fahimi@sbmu.ac.ir

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

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
comparision 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 pharmaceutics, Responsible pharmacist

Other areas of specialty/work

Street address

No 19, Tirdada alley, Aliakbari st., Motahari st.

City

Tehran

Postal code

Phone

+98 21 8854 7515

Fax

Email

r.saadati@sadafdarousaba.com;
f.shahrokhi@sadafdarousaba.com

Web page address

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

Street address

Niayesh-Valiasr crossing, Faculty of pharmacy

City

Tehran

Postal code

Phone

+98 21 8805 0939

Fax

Email

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