

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Assessment of the efficacy of concomitant administration of nebulized lasix and salbutamol on spirometric indices of patients with persistent asthma

Protocol summary

Summary

Nonsmoker patients between range of 18 to 75 yr with a history of persistent asthma that do not have heart disease, other underlying disease(diabetes mellitus, hypertension, malignancy, bronchiectasis and ...) or respiratory diseases other than asthma and don't use any medications except for asthma included in the trial. Data are gradually gathered in a sequential trial. In this trial asthma diagnosis basis is history of cough, sputum, intermittent and variable dyspnea, wheezing, and chest tightness for at least 6 months. Chest x ray should be free of fibrosis, lobar pneumonia, bronchiectasis, and mass. Diagnosis of asthma has been confirmed previously by subspecialists. Initially for patients who arrive trial a physician fills a questionnaire for age, gender, and other variables. One part of questionnaire belongs to estimating persistent asthma severity and based on frequency of daily and nocturnal asthma attacks patients are divided into three groups of mild, moderate and severe persistent asthma. Then after patient is tested by a spirometry and its indices are recorded. In order to simulate both groups of patients before administering nebulizers, on the basis of age asthma underlying persistent severity physician and spirometry indices decides which patient is included in case or control group. Then patient is settled in a silent room and receives a nebulized salbutamol(2.5mg) or nebulized lasix(10mg) plus salbutamol(2.5mg) diluted in 1 cc instilled water. Fifteen minutes after nebulizer finished a repeated spirometry is done and indices are recorded. For all patients spirometry machine and nebulizer equipments are the same.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104136187N1**

Registration date: **2011-07-10, 1390/04/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-10, 1390/04/19

Registrant information

Name

Mohammadi Saba

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0021

Email address

saba-ma@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2011-04-09, 1390/01/20

Expected recruitment end date

2012-01-10, 1390/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the efficacy of concomitant administration

of nebulized lasix and salbutamol on spirometric indices of patients with persistent asthma

Public title

Efficacy of concomitant administration of nebulized lasix and salbutamol on spirometric indices of asthmatic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Asthma diagnosis based on signs of cough, sputum, intermittent and variable dyspnea, wheezing, and chest tightness for at least 6 months; diagnosis of asthma has been confirmed previously by specialists using following criteria: decline of FEV1/FVC, PEF, FEV1 and increasing FEV1>12% and >200ml after 15 min receiving short acting beta2 agonist or consuming corticosteroids orally for 2-4 weeks (prednisolone 30-40 mg daily). Among asthmatic patients only those who have persistent asthma (i.e. at least more than 2 nocturnal attacks per month and/or at least more than 2 daily attacks per week) are eligible cases.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **54**

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

Kashan University of Medical Science

Street address

Bolvard Ghotb Ravandi, Kilometer5

City

Kashan

Postal code

8713781147

Approval date

2011-03-16, 1389/12/25

Ethics committee reference number

29/5/1/3643/پ

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

FEV1(forced expiratory volume in 1 second) improvment

Timepoint

30 minute after nebulization

Method of measurement

Spirometry

2

Description

FVC(forced expiratory vital capacity) improvment

Timepoint

30 minute after nebulization

Method of measurement

Spirometry

3

Description

MMEF(maximum midexpiratory flow) improvment

Timepoint

30 minute after nebulization

Method of measurement

Spirometry

4

Description

Peak expiratory flow improvment

Timepoint

30 minute after nebulization

Method of measurement

Spirometry

Secondary outcomes

1

Description

Bronchospasm

Timepoint

30 minute after nebulization

Method of measurement

Clinical evaluation

Intervention groups

1

Description

2.5 mg salbutamol +10 mg furosemide is nebulized in intervention group for 30 minute

Category

Treatment - Drugs

2

Description

2.5 mg salbutamol is nebulized in control group for 30 minute

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital

Full name of responsible person

Dr Mohammadali Saba

Street address

km5 ghotb ravandi blv

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Dr Gholamreza Hamidi

Street address

Shahid Beheshti Hospital

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kashan University of Medical Sciences

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

kashan university of medical sciences

Full name of responsible person

Dr Mohammadali Saba

Position

assisstan professor

Other areas of specialty/work

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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