Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Name of organization / entity
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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 salbuthamol +10 mg furosemide is nebulized in intervention group for 30 minute
Category
Treatment - Drugs

2

Description
2.5 mg salbuthamol 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
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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
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Shahid Beheshti Hospital
City
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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
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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