

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Sep 2026

Determination of time and amount of hyper tonic saline required to induce a 15% FEV1 decrease in asthmatic patients with FEV1>60% predicted

Protocol summary

Summary

In this study 50 patients suffering from asthma who have referred to Kashan's Beheshti Hospital in 1390 will be recruited. The patients will be observed completely by a doctor who is expert in respiratory diseases. Asthmatic patients with FEV1>=60% will be enrolled in this investigation; afterward these patients will be exposed to ultrasonic nebulizer with stable amount of nebulized hypertonic saline in 0.5, 1, 2, 4 and 8 minutes and during these times FEV1, PEF, FEF25-75 and FVC will be measured. The nebulization will be continued till a 15% decrease in FEV1 or 20% decrease in PEF happens. In this condition value of hypertonic saline, spent time & changes in FEF25-75 and FVC would be inserted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104266187N2**

Registration date: **2011-07-18, 1390/04/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-07-18, 1390/04/27

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

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of time and amount of hyper tonic saline required to induce a 15% FEV1 decrease in asthmatic patients with FEV1>60% predicted

Public title

Determination of time and amount of hyper tonic saline required to induce a 15% FEV1 decrease in asthmatic patients referred to shahid beheshti hospita, Kashan

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: asthmatic patients, age between 15 to 60 with FEV1>60% Exclusion criteria: pneumonia; bronchiectasia, advance interstitial lung disease; pulmonary fibrosis; chronic obstructive pulmonary disease and valvular & congenital heart disease.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotb ravandi boulevard km5

City

Kashan

Postal code

87159/88141

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

p29513532

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45.8

ICD-10 code description

Mixed asthma

Primary outcomes

1

Description

15% decrease in FEV1

Timepoint

0.5 minute

Method of measurement

Spirometry

2

Description

15% decrease in FEV1

Timepoint

1 minute

Method of measurement

spirometry

3

Description

15% decrease in FEV1

Timepoint

2 minute

Method of measurement

spirometry

4

Description

15% decrease in FEV1

Timepoint

4 minute

Method of measurement

spirometry

5

Description

15% decrease in FEV1

Timepoint

6 minute

Method of measurement

spirometry

6

Description

15% decrease in FEV1

Timepoint

8 minute

Method of measurement

spirometry

Secondary outcomes

1

Description

20% decrease in PEF

Timepoint

0.5 minute

Method of measurement

spirometry

2

Description

20% decrease in PEF

Timepoint

1 minute

Method of measurement

spirometry

3

Description

20% decrease in PEF

Timepoint

2 minute

Method of measurement

spirometry

4

Description

20% decrease in PEF

Timepoint

4 minute

Method of measurement

spirometry

5

Description

20% decrease in PEF

Timepoint

6 minute

Method of measurement

spirometry

6

Description

20% decrease in PEF

Timepoint

8 minute

Method of measurement

spirometry

Intervention groups

1

Description

Intervention: The patients will be exposed to ultrasonic nebulizer with stable amount of nebulized hypertonic saline in 0.5, 1, 2, 4 and 8 minutes. The nebulization will be continued till a 15% decrease in FEV1 or 20% decrease in PEF

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

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

Kashan University of Medicine Sciences

Full name of responsible person

Dr Gholamreza Hamidi

Street address

km 5 Ghotb Ravandi Blv

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan University of Medicine 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 Medicine Sciences

Full name of responsible person

Dr. Mohammad ali saba

Position

Assistant professor

Other areas of specialty/work

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saba-ma@kaums.ac.ir

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Kashan University of Medicine Sciences

Full name of responsible person

Dr Mohammadali Saba

Position

Assistant Professor

Other areas of specialty/work**Street address**

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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