Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The effect of peak expiratory flowmeter on timing indicators and mistriage among chronic obstructive pulmonary disease patients with dyspnea

Protocol summary

Study aim
Determining the effect of expiratory peak flow meter on time indices and triage error in patients with chronic obstructive pulmonary dysfunction

Design
Clinical trial with intervention and control groups, randomized, parallel, blind.

Settings and conduct
Sampling is performed at the Edalatian Emergency Department of Imam Reza Hospital in three shifts (morning, evening and night). A pilot study is used to determine the final sample size. In this method, the researcher is fully aware of of the intervention, and a full description of the procedure is presented to the patient in the intervention group. But in the next step, the members of the treatment team, including the emergency doctor, consultants, and nurses responsible for the patient and outcome assessor are not aware of patients assigned group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The patients formally consent to participate in the research. The age of the patients are over 18 years. The patients' chief complaint is shortness of breath. The patients have a history of chronic obstructive pulmonary disease. Exclusion criteria: The patient can not use peak flow meter. The patient has a history of chest trauma. Patient file is incomplete or defective. The patient is transferred to other centers. No diagnosis of COPD.

Intervention groups
In intervention group, Peak flowmeter is used to assess respiratory function and based on the result, patient is prioritized by emergency severity index scale.

Main outcome variables
Time to Physician Visit, Time to Physician Visit, Time to First Oxygen Therapy and Triage Levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180410039258N1**
Registration date: **2018-11-08, 1397/08/17**
Registration timing: **retrospective**

Last update: **2018-11-08, 1397/08/17**
Update count: **0**

Registration date
2018-11-08, 1397/08/17

Registrant information

Name
Mahin Hamechizfahm roudi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5423 5781

Email address
hamechifahmm941@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-23, 1397/04/02

Expected recruitment end date
2018-08-24, 1397/06/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of peak expiratory flowmeter on timing indicators and mistriage among chronic obstructive pulmonary disease patients with dyspnea

Public title
The effect of peak expiratory flowmeter on timing indicators and mistriage among chronic obstructive pulmonary disease patients with dyspnea

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
The patient who signs informed consent to participate in the research. The age of the patient is over 18 years. The chief complaint of patient is shortness of breath. The patient has a history of chronic obstructive pulmonary disease.

Exclusion criteria:
The patient is not consented to participate further in the research. Patient file is incomplete. The patient is transferred to the other centers. The patient is unable to perform peak expiratory flowmetery. The patient do not have a history of chest trauma or surgery.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients included into the study are randomly assigned into the intervention or control groups. Black and white cards are randomly sorted (black for intervention and white for control group). After inclusion, a card is picked up and patient is assigned to the intervention or control group based on the card color.

Blinding (investigator's opinion)
Double blinded

Blinding description
After intervention in triage room, patients is introduced to the emergency department via routine triage form. Therefore, it is not possible to recognize subjects by physicians and nurses in the emergency room.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Regional Ethics Committee on Medical Research

Street address
Ibn Sina st. - Imam Reza Hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Approval date
2018-06-30, 1397/04/09

Ethics committee reference number
IR.MUMS.REC.1397.083

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease

ICD-10 code
J44.1

ICD-10 code description
Chronic obstructive pulmonary disease with (acute) exacerbation

Primary outcomes

1

Description
timing indicators

Timepoint
Time to emergency physician- time to specialist visit- time to oxygen therapy

Method of measurement
digital clock

Secondary outcomes

1

Description
Triage level

Timepoint
Right after intervention

Method of measurement
Emergency severity index

Intervention groups

1

Description
Patients in the intervention group is triaged by adding a

standard expiratory peak flow meter to the emergency severity index. The peak flow meter shows red, yellow, and green states. Patient is educated to take a deep inspiration and then sealed the lips tightly around the mouthpiece In order to make sure that no air leaks out around the lips, then, perform an rapid expiration into the device. Level 2 is assigned in case of red or O2SAT <92%. Level 3 is assigned in case of yellow or need to more than 2 resources. Level 4 is assigned in case of green or need to only one resource. Level 5 is assigned in case of green or no need to additional resources.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Mahin hamechizfahm rudi
Street address
Ibne Sina - Imam Reza Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2000
Email
Hamechifahmm941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Ghreshi Building - Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2000
Email
hamechifahmm941@mums.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahin Hamechizfahm rudi
Position
Post-graduate student of Medical-Surgical Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Street of Avicenna - Imam Reza Imam (AS)
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2000
Email
hamechifahmm941@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahin Hamechizfahm rudi
Position
Graduate student of Internal-Surgical Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Vahdat-Vahdat Street 3
City
khaf
Province
Razavi Khorasan
Postal code
9561648785

Phone
+98 51 5422 2607
Email
hamechifahmm941@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahin Hamechizfahm Rudi
Position
Graduate student of Internal-Surgical Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Vahdat-Vahdat Street 3
City
khaf
Province
Razavi Khorasan
Postal code
95616-48785
Phone
+98 51 5422 2607
Email
hamechifahmm941@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only a portion of the data, such as the original outcome information, is shared
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Data will only be available to researchers in universities
Under which criteria data/document could be used
In order to conduct research related to this research
From where data/document is obtainable
To receive data, applicants can email the following by e-mail hamechifahmm941@mums.ac.ir
What processes are involved for a request to access data/document
At the first request, applicants will be given the opportunity to file
Comments