

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Rapid Shallow Breathing Index Survey: A Predictor of Non-Invasive Ventilation Necessity in Patients with Chronic Obstructive Pulmonary Disease Exacerbation: A prospective descriptive study

Protocol summary

Summary

In a prospective descriptive study, ninety eight patients over 40 years old with documented COPD exacerbation who were referred to emergency department of Imam Reza hospital, Tabriz, Iran were studied. In the present study, we aimed at evaluating the use of Rapid Shallow Breathing Index (a ratio determined by the frequency (f) divided by the tidal volume (VT).) In NIV requirement in COPD patients. Also, ABG parameters and APACHE II scoring were measured in each patient. The inclusion criteria were: All the patients over 40 years old, COPD Exacerbation, History of smoking at least twenty pack/year. The exclusion criteria: Respiratory arrest, cardiovascular instability, lack of patient cooperation, upper airway obstruction, possibility of increased aspiration risk, morbid obesity, increase in secretions, recent facial trauma or gastroesophageal surgery, impaired mask fixation, nasopharyngeal abnormalities, craniofacial trauma, lack of patient consent. To determine the need for NIV, in all patients, ABG and simultaneous RSBI were measured using ventilator model "Vector ST40" with BLPAP mode EPAP=5 cm H₂O, IPAP=10 cm H₂O. Furthermore, medical treatments (intravenous corticosteroid, salbutamol spray, atrovent spray, antibiotics, and oxygen therapy) were administered. Furthermore, medical treatments (intravenous corticosteroid, salbutamol spray, atrovent spray, antibiotics, and oxygen therapy) were administered. Duration and method of oxygen therapy was as following for all patients: Indications for commencement of non-invasive ventilation (NIV) included exacerbation of COPD with PH<7.35 and PaCO₂>45mmHg or PaO₂<60mmHg (SpO₂<90%) despite receiving Max FIO₂ of 60%. Titrated Oxygen therapy was initiated using Venturi mask at FIO₂ of 24% to 60% for all patients based on pulse oximetry every 20 minutes to achieve SpO₂>90% (for maximum of two

hours). In case of not achieving SPO₂>90% despite receiving FIO₂>60%, patients underwent NIV. After administering the above-mentioned treatments and oxygen therapy for two hours, required variables on admission, one hour and two hours after admission were measured; ultimately patients were divided into two groups of requiring non-invasive ventilation (group I) and not requiring non-invasive ventilation (group II). Patients requiring non-invasive ventilation were hospitalized after consulting with a pulmonologist and patients who were not hospitalized or did not require non-invasive ventilation, depending on clinical condition.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304282496N10**

Registration date: **2013-04-29, 1392/02/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-04-29, 1392/02/09

Registrant information

Name

Hassan Soleimanpour

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete
Funding source
Vice chancellor for research, Tabriz University of Medical Sciences, Iran

Expected recruitment start date
2011-03-01, 1389/12/10

Expected recruitment end date
2011-08-30, 1390/06/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Rapid Shallow Breathing Index Survey: A Predictor of Non-Invasive Ventilation Necessity in Patients with Chronic Obstructive Pulmonary Disease Exacerbation: A prospective descriptive study

Public title
Rapid Shallow Breathing Index Survey: A Predictor of Non-Invasive Ventilation Necessity in Patients with Chronic Obstructive Pulmonary Disease Exacerbation: A prospective descriptive study

Purpose
Diagnostic

Inclusion/Exclusion criteria
The inclusion criteria: all the patients over 40 years old; COPD exacerbation; history of smoking at least twenty pack/year. Exclusion criteria: respiratory arrest; cardiovascular instability; lack of patient cooperation; upper airway obstruction; possibility of increased aspiration risk; morbid obesity; increase in secretions; recent facial trauma or gastroesophageal surgery; impaired mask fixation; nasopharyngeal abnormalities; craniofacial trauma; lack of patient consent.

Age
From **40 years** old to **100 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
N/A

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

Research-Vice chancellor, Tabriz University of Medical Sciences, Iran

Street address

Research Vice chancellor of Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN.

City

Tabriz

Postal code

51664

Approval date

2010-01-09, 1388/10/19

Ethics committee reference number

883

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease Exacerbation

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with acute exacerbation, unspecified

Primary outcomes

1

Description

Rapid Shallow Breathing Index

Timepoint

On admission, one hour and two hours after admission

Method of measurement

A ratio determined by the frequency (f) during one minute divided by tidal volume (VT)

Secondary outcomes

1

Description

Acute Physiology And Chronic Health Evaluation II

Timepoint

On admission, one hour and two hours after admission

Method of measurement

Temperature; heart rate; hematocrit; white blood cell count; respiratory rate; PaO₂/FIO₂; creatinine, PH, Na, K, GCS Score and blood pressure

Intervention groups

1

Description

All patient's RSBI were measured using ventilator model "Vector ST40" with BLPAP mode EPAP=5 cm H2O, IPAP=10 cm H2O.

Category

Diagnosis

2

Description

Arterial blood gas (ABG) sampling from patients

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Hassan Soleimanpour

Street address

Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN. Tabriz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Shakouri, M. D.

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Research Vice chancellor of Tabriz University of Medical Sciences ,Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN

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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

Research Vice chancellor of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hassan Soleimanpour

Position

Anesthesiologist/ Associate professor of Anesthesiology, MD

Other areas of specialty/work

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

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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