

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 H<sub>2</sub>O, IPAP=10 cm H<sub>2</sub>O. 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 PaCO<sub>2</sub>>45mmHg or PaO<sub>2</sub><60mmHg (SpO<sub>2</sub><90%) despite receiving Max FIO<sub>2</sub> of 60%. Titrated Oxygen therapy was initiated using Venturi mask at FIO<sub>2</sub> of 24% to 60% for all patients based on pulse oximetry every 20 minutes to achieve SpO<sub>2</sub>>90% (for maximum of two

hours). In case of not achieving SPO<sub>2</sub>>90% despite receiving FIO<sub>2</sub>>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)

###### Phone

+98 41 1329 1286

###### Email address

soleimanpourh@tbzmed.ac.ir

##### 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; PaO<sub>2</sub>/F<sub>1</sub>O<sub>2</sub>; 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

Tabriz

## 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.

#### 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

### 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

#### Street address

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

#### City

Tabriz

#### Postal code

51664

#### Phone

+98 41 1335 2078

#### Fax

+98 41 1335 2078

#### Email

h\_mofid1357@yahoo.com

#### Web page address

## Person responsible for scientific 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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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Hassan Soleimanpour

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Anesthesiology, MD

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

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**Web page address**

## 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*