# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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
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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; rdiovascular 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/F1O2; 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
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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**
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**Full name of responsible person**
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**Position**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*