

# How do we predict if a pressurized breathing mask might fail in supporting our patients?

<b>Submission date</b> 05/09/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/09/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 17/09/2020	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Patients who get sick from pneumonia and require a breathing machine are at high risk of complications and death. Doctors start treating them with oxygen masks with oxygen given under higher pressure than normal air (termed non-invasive ventilation) before they switch to breathing machines. This approach is much less aggressive with an expected lower level of complications. The aim of this study is to find out how to tell whether a person needs a breathing machine.

### Who can participate?

Patients who need help with their breathing because they have pneumonia

### What does the study involve?

The researchers start treating the patients with non-invasive ventilation and collect some measurements until they complete 2 full days of assisted breathing. They do not interfere with treatment or advocate a certain way of treatment.

### What are the possible benefits and risks of participating?

Patients receive optimal treatment and will be observed frequently and will be attended to if needed.

### Where is the study run from?

Cairo University Hospitals (Egypt)

### When is the study starting and how long is it expected to run for?

February 2019 to June 2020

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr Walid Ahmed

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# Contact information

## Type(s)

Scientific

## Contact name

Dr Walid Ahmed

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

MS-180-2019

# Study information

## Scientific Title

Clinical and radiological predictors of early non-invasive ventilation failure in pneumonia patients with acute lung injury

## Study objectives

The main objective is to identify contributing factors to early NIV failure within the first 48 hours in pneumonia with acute lung injury.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 08/01/2020, Cairo University Faculty of Medicine Research Ethics Committee (Dr Amr El Sayed Fouad El Hadidy; +20 (0)1223103336; elhadidyamr@gmail.com), ref: MS-180-2019

## Study design

Observational cohort study

## Primary study design

Observational

## Study type(s)

Diagnostic

## Health condition(s) or problem(s) studied

Prediction of non-invasive failure in pneumonia patients with acute lung injury

## Interventions

All patients admitted to the ICU for NIV due to pneumonia with hypoxemic respiratory failure and mild to moderate ARDS i.e. P/F ratio  $<300$ , are enrolled in the study. Diagnosis of pneumonia is established upon clinical findings and radiologic findings, compatible with pneumonia diagnosis. Patients are subsequently excluded due to presence of do-not-intubate orders, presence of chronic obstructive pulmonary disease, requirement for emergency intubation, severe ARDS i.e. P/F ratio  $<150$  and NIV intolerance. NIV intolerance is defined as patient refusal for NIV because of discomfort. Informed consent is obtained from patients or their family members. The decision to initiate NIV is made by the attending physicians based on the following criteria: clinical presentation of respiratory distress at rest, partial pressure of arterial oxygen (PaO<sub>2</sub>) of  $<60$  mmHg or a PaO<sub>2</sub>/fraction of inspired oxygen (FiO<sub>2</sub>) ratio of  $<300$  with supplemental oxygen.

The NIV is managed by attending physicians. Patients are placed in a semi-recumbent position to avoid aspiration, assuming there is no contraindication to this position. The positive-end expiratory pressure is maintained at 4–8 cmH<sub>2</sub>O. Inspiratory pressure is initially set at 10 cmH<sub>2</sub>O (above zero) and then increased in increments of 2 cmH<sub>2</sub>O to achieve the best control of dyspnea and tolerance of the patient. If a patient does not tolerate 10 cmH<sub>2</sub>O of inspiratory pressure, the latter is decreased to 8 even further to 6 cmH<sub>2</sub>O, if needed. The fractional concentration of oxygen is set to achieve peripheral oxygen saturation of  $>92\%$ . At the beginning of treatment, continuous use of NIV is encouraged. Non-invasive ventilation is used intermittently until the patient can be completely weaned from it.

Early NIV failure is defined as a requirement of intubation after NIV intervention, within 48 hours window, based on the following criteria: respiratory or cardiac arrest, failure to maintain a PaO<sub>2</sub>/FiO<sub>2</sub> of  $>100$ , development of conditions necessitating intubation to protect the airway (coma or seizure disorders) or to manage copious tracheal secretions, inability to correct dyspnea, lack of improvement of signs of respiratory muscle fatigue, and hemodynamic instability without response to fluids and vasoactive agents.

HACOR is recorded at NIV institution, 1 hour later, 12 hours later, 24 hours later if NIV is still used.

Lung ultrasound score (LUS) is performed using a 2- to 4-MHz convex probe. Patient position is supine and lateral decubitus positions. Each lung is divided into three zones and is examined anteriorly and posteriorly to assess the degree of lung aeration with a total of 12 zones examined. Four aeration patterns by ultrasound are defined: 1) Normal aeration: the presence of lung sliding with A-lines or less than two isolated B lines; 2) Moderate loss of lung aeration: multiple B lines (B1 lines); 3) Severe loss of lung aeration: multiple fused B lines (B2 lines); and 4) Lung consolidation (C), the presence of a dynamic air bronchograms and tissue pattern, N = 0, B1 lines = 1, B2 lines = 2, C = 3. The final score, ranging from 0 to 36, is the sum of the values, from 0

to 3, assigned to the LUS patterns visualized in each of the 12 regions examined. Lung ultrasound score is recorded at NIV institution, 12 hours and 24 hours later. Lung ultrasound score divided patients into six distinct categories (1: LUS 0-6, 2: LUS 7-12, 3: LUS 13-18, 4: LUS 19-24, 5: LUS 25-30, 6: LUS 31-36). To document tissue hypoperfusion, lactate is measured at NIV institution and repeated 12 hours and 24 hours later. It is recorded in mmol/l.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Primary outcome(s)**

NIV failure, defined as the transition of the patient to invasive ventilation due to worsening clinical condition (drop in blood pressure or drop in conscious level), worse blood gases (increase in carbon dioxide or drop in oxygen), or patient refusal to continue on non-invasive ventilation. Timepoints: within the first 48 hours of non-invasive intervention.

### **Key secondary outcome(s)**

Prediction of non-invasive failure using the HACOR score calculated at 0, 1, 12, 24 hours

### **Completion date**

30/06/2020

## **Eligibility**

### **Key inclusion criteria**

1. All patients admitted to the ICU for NIV due to pneumonia with hypoxemic respiratory failure and mild to moderate ARDS i.e. P/F ratio <300
2. Diagnosis of pneumonia established upon clinical findings and radiologic findings, compatible with pneumonia diagnosis

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Sex**

All

### **Total final enrolment**

177

### **Key exclusion criteria**

1. Presence of do-not-intubate orders
2. Presence of chronic obstructive pulmonary disease

3. Requirement for emergency intubation
4. Severe ARDS i.e. P/F ratio < 150
5. NIV intolerance

**Date of first enrolment**

01/02/2020

**Date of final enrolment**

30/06/2020

## **Locations**

**Countries of recruitment**

Egypt

**Study participating centre**

**Cairo University**

Critical Care Department

Faculty of Medicine

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**Study participating centre**

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**Study participating centre**

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**Study participating centre****El Haram Hospital**

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Giza

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## Sponsor information

**Organisation**

Cairo University Hospitals

**ROR**

<https://ror.org/058djb788>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Walid Ahmed ([walidkamel@cu.edu.eg](mailto:walidkamel@cu.edu.eg)).

**IPD sharing plan summary**

Available on request