ISRCTN14641518 https://doi.org/10.1186/ISRCTN14641518

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

Submission date
05/09/2020

Recruitment status
No longer recruiting

Registration date
17/09/2020

Overall study status
Completed

Last Edited
17/09/2020

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
walidkamel@cu.edu.eg

Contact information

Type(s)
Scientific

Contact name
Dr Walid Ahmed

ORCID ID
https://orcid.org/0000-0003-0248-9498

Contact details
7110 Meerag city
Carrefour Maadi
Cairo
Egypt
11436
+20 (0)1111632486
walidkamel@cu.edu.eg

Additional identifiers

Clinical Trials Information System (CTIS)
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_2) of <60 mmHg or a PaO_2/fraction of inspired oxygen (FiO_2) 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_2O. Inspiratory pressure is initially set at 10 cmH2O (above zero) and then increased in increments of 2 cmH_2O to achieve the best control of dyspnea and tolerance of the patient. If a patient does not tolerate 10 cmH_2O of inspiratory pressure, the latter is decreased to 8 even further to 6 cmH_2O, 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_2 /FiO_2 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
Kasr Alainy
el Sarayat street
Manyal
Cairo
Egypt
11562

Study participating centre
Elkatib
17 Dr.Abdallah Elkatib
Vieny Square
Dokki
Cairo
Egypt
12654

Study participating centre
Dr. M. El Shabrawishy Hospital
14 Vieny Square
Dokki
Cairo
Egypt
12654

Study participating centre
Al Assema hospital
Ahmed Samy st.

Agouza
Cairo
Egypt
12654

Study participating centre
El Haram Hospital
Omraneya, Haram
Giza
Egypt
12556

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).

IPD sharing plan summary
Available on request