Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of esophageal pressure measurement for non-invasive positive pressure ventilation (NIPPV) regulation for the prevention of pulmonary barotrauma in comparison with control group in patients with Covid 19 undergoing respiratory support admitted to the intensive care unit

Protocol summary

Study aim
Evaluation of the effect of esophageal pressure measurement for non-invasive positive pressure ventilation (NIPPV) regulation for the prevention of pulmonary barotrauma in comparison with control group in patients with Covid 19 undergoing respiratory support admitted to the intensive care unit

Design
Clinical trial with control group, double-blind, randomized, phase 2 on 90 patients. Randomizer softwere was used for randomization.

Settings and conduct
Patients with Covid 19 admitted to the intensive care unit of Imam Reza Hospital are included in the study and are divided into two groups. The first group is adjusted by measuring the intraesophageal pressure and the second group is adjusted by their non-invasive ventilation settings based on anesthesia instructions. The researcher and statistical analyst do not notice the study groups. Finally, the data are evaluated for their effectiveness in reducing barotrauma.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with Covid 19 with positive PCR or CT scan, hospitalized in the intensive care unit, patient is receiving non-mechanical ventilation, patient should be fed through the gastric feeding tube (NG tube)

Intervention groups
Patients are divided into two groups. The first group measures their non-invasive ventilation settings by measuring their intraesophageal pressure; the second group measures their non-invasive ventilation settings based on anesthesia instructions.

Main outcome variables
Baro trauma

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200612047740N4**
Registration date: **2022-06-18, 1401/03/28**
Registration timing: **prospective**

Last update: **2022-06-18, 1401/03/28**
Update count: **0**

Registration date
2022-06-18, 1401/03/28

Registrant information

Name
Hossein Naderi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3568 5233

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-21, 1401/03/31

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of esophageal pressure measurement for non-invasive positive pressure ventilation (NIPPV) regulation for the prevention of pulmonary barotrauma in comparison with control group in patients with Covid 19 undergoing respiratory support admitted to the intensive care unit

Public title

The effect of esophageal pressure measurement to prevent pulmonary barotrauma in patients with Covid 19 undergoing respiratory support

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Covid 19 with positive PCR or CT scan Hospitalized in the intensive care unit Patient is receiving non-mechanical ventilation Patient should be fed through the gastric feeding tube (NG tube) Informed consent of the patient or his legal guardian

Exclusion criteria:

Coagulation disorders Gastrointestinal bleeding History of fractures and trauma to the base of the skull

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to the groups of A and B using Randomization software (https://www.randomizer.org/) according to inclusion criteria. Each group has 45 members. In this software, numbers from 1 to 90 are entered into the software and at one time, they randomly pick the numbers from one to ninety so that the number of people in each group is equal. The numbers remain hidden and the order in which people enter the study is revealed in the order in which the data output software is displayed, and if the number is between 1 and 45, it is placed in the first group and if it is between 46 and 90, it is placed in the second group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are divided into two groups A and B and are kept in two separate parts. How to do the study for each group is described. The information is collected by the clinical caregiver and the researcher and data analyzer do not know the patient group and after analyzing the data, the codes are decoded to avoid bias.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AJA University of Medical

Street address

AJA university of medical sciences, Shahid Etemadzade st, West Fatemi st

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Province

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Postal code

1411718541

Approval date

2022-02-20, 1400/12/01

Ethics committee reference number

IR.AJAUMS.REC.1400.305

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U.07

ICD-10 code description

COVID-19 Disease

Primary outcomes

1

Description

Intra esophageal pressure

Timepoint

Intraesophageal pressure is measured twice daily (morning and evening) while receiving non-invasive ventilation while the patient is in the intensive care unit(ICU)

Method of measurement

Manometer

2

Description

Number of people with barotrauma

Timepoint

From the start of non-invasive ventilation to the onset of barotrauma

Method of measurement

Observe and record

Secondary outcomes

1

Description

Oxygen saturation

Timepoint

It is measured twice daily (morning and evening) while receiving non-invasive ventilation while the patient is in the intensive care unit(ICU).

Method of measurement

Pulse oximeter

2

Description

Duration of stay in the intensive care unit

Timepoint

From the time of entering the intensive care unit until the time of discharge or the time of death

Method of measurement

Observe and record

3

Description

Trans pulmonary pressure

Timepoint

Trans pulmonary pressure is measured twice daily (morning and evening) while receiving non-invasive ventilation while the patient is in the ICU.

Method of measurement

Manometer

4

Description

Time of barotrauma

Timepoint

Number of days from the start of non-invasive ventilation to the onset of barotrauma

Method of measurement

Observe and record

Intervention groups

1

Description

Intervention group: Patients's nasogastric tube is pulled up and connected to a manometer and their intraesophageal pressure is measured. Ventilation settings are adjusted so that the difference in pulmonary pressure remains between 0-10 cm of water and if it is more than 35 to 40 cm of water, the settings of the device are reduced and no trauma occurs. Finally, the incidence of barotrauma in this group is measured.

Category

Prevention

2

Description

Control group: Patients in this group do not have daily intraesophageal pressure measurements. Ventilation settings of patients in this group are controlled through anesthesia instructions set by the anesthesiologist (project manager) and the incidence of barotrauma in this group is measured.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Mohammadreza Rafiee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Mojtaba Yousefi

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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
Artesh University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
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Hossein Naderi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Only registered symptoms can be published without mentioning the names of the participants
When the data will become available and for how long

Start of access period 6 months after printing the results up to one year after printing

To whom data/document is available

Only available to scholars working in academia and academia

Under which criteria data/document could be used

Written request via email(hossein.naderi1374@gmail.com) and university approval

From where data/document is obtainable

By contacting the corresponding author

What processes are involved for a request to access data/document

After the email is received by the applicant, it takes one week to agree The university will be obtained and then will be notified to the requestor. Maximum of this process takes ten days.

Comments