Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Using HACOR score in predicting failure of non-invasive ventilation in patient with Type-I respiratory failure

Protocol summary

Study aim

Our study aims to assess the predictive validity of the HACOR score in our demographic area for diagnosing non-invasive ventilation (NIV) failure in patients diagnosed with type-1 respiratory failure assessed after one hour of NIV therapy irrespective of the cause of respiratory failure.

Design

Prospective, single center, single blinded, interventional study

Settings and conduct

HACOR score to be assessed by the consultant on duty one hour before and after being on CPAP therapy blinded to the study protocol

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients with Pa02/FiO2 levels < 300 mmHg and PaCO2 levels less than 45 mmHg with PaO2 and PaCO2 (calculated by ABG (arterial blood gas) analysis) at room air or not maintaining ratio at low oxygenation therapy after administration of oxygen at FiO2 of 0.30 Exclusion criteria included patients with severe cardiorespiratory compromise, critical patients on vasopressor support, patients with poor lung compliance unable to breath in CPAP, intubated patients or those intubated less than 1 hour of CPAP, patients with a previous failed CPAP trial or on HFNO (high flow nasal oxygenation) in the last 72 hours, patients non-compliant on CPAP despite sedation and patients not willing to be included in the study.

Intervention groups

One interventional group studies for the HACOR score and its predictive validity for NIV failure before and after one hour on CPAP therapy

Main outcome variables

Primary variables studied were success and failure of CPAP therapy and accuracy of prediction of the HACOR score for NIV failure after 1 hour of therapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231101059927N1**
Registration date: **2023-11-07, 1402/08/16**
Registration timing: **retrospective**

Last update: **2023-11-07, 1402/08/16**
Update count: **0**

Registration date

2023-11-07, 1402/08/16

Registrant information

Name
Ali Aftab
Name of organization / entity
PNS Shifa Hospital Karachi
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Pakistan
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alijiwani512@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-09-30, 1402/07/08

Actual recruitment start date

2022-12-01, 1401/09/10

Actual recruitment end date

2023-09-30, 1402/07/08

Trial completion date

2023-09-30, 1402/07/08

Scientific title
Using HACOR score in predicting failure of non-invasive ventilation in patient with Type-I respiratory failure

Public title
HACOR score in predicting non-invasive ventilation failure

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Pa02/FiO2 levels < 300 mmHg and PaCO2 levels less than 45 mmHg with PaO2 and PaCO2 (calculated by ABG (arterial blood gas) analysis) at room air or not maintaining ratio at low oxygenation therapy after administration of oxygen at FiO2 of 0.30

Exclusion criteria:
Patients with severe cardiorespiratory compromise Critical patients on vasopressor support Patients with poor lung compliance unable to breath in CPAP Intubated patients or those intubated less than 1 hour of CPAP Patients with a previous failed CPAP trial or on HFNO (high flow nasal oxygenation) in the last 72 hours Patients non-compliant on CPAP despite sedation Patients unwilling to be included in the study

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Investigator

Sample size
Target sample size: **180**
Actual sample size reached: **180**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinded of the study protocol and given a standard monitoring chart to endorse vitals and clinical variables to be later assessed by the outcome assessor

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Review Board PNS Shifa Karachi

Street address
PNS Shifa

City
Karachi

Postal code
75300

Approval date
2022-11-30, 1401/09/09

Ethics committee reference number
PNS-KCI-00100

Health conditions studied

1

Description of health condition studied
Type-I respiratory failure

ICD-10 code
J96.0

ICD-10 code description
Acute respiratory failure

Primary outcomes

1

Description
Failure of NIV after 1-hour on CPAP therapy

Timepoint
1 hour after CPAP therapy

Method of measurement
Standard HACOR score

2

Description
Sensitivity and specificity of HACOR in predicting NIV failure

Timepoint
1 hour after being on CPAP therapy

Method of measurement
Assessment using standard SPSS software

3

Description
Postive and negative predictive value of the HACOR test in assessing NIV failure

Timepoint
1 hour after being on CPAP therapy

Method of measurement
Standard statistical SPSS software

Secondary outcomes

1

Description
Heart rate and mean arterial pressure

Timepoint
Before and after 1 hour of CPAP therapy

Method of measurement
Cardiac monitor

2

Description
Respiratory rate
Timepoint
Before and after 1 hour of CPAP therapy
Method of measurement
Standard respiratory monitor

3

Description
Glasgow coma scale
Timepoint
Before and after 1 hour of CPAP therapy
Method of measurement
Standard Glasgow coma scale

4

Description
Pa02/FiO2 ratio
Timepoint
Before and after 1 hour of CPAP therapy
Method of measurement
Using arterial blood gas samples and standard calculating formula

Intervention groups

1

Description
Intervention group: HACOR SCORE GROUP
Category
Early detection

Recruitment centers

1

Recruitment center
Name of recruitment center
PNS Shifa Karachi
Full name of responsible person
Dr Ali Aftab
Street address
PNS Shifa
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64200
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Email
alijiwani512@hotmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
PNS Shifa Karachi
Full name of responsible person
Dr Ali Aftab
Street address
PNS Shifa
City
Karachi
Postal code
64200
Phone
+92 300 2509354
Email
alijiwani512@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
PNS Shifa Karachi
Proportion provided by this source
1
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
PNS Shifa Hospital Karachi
Full name of responsible person
Ali Aftab
Position
Consultant
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Word document of the manuscript along with output sheet of SPSS software would be made available
When the data will become available and for how long
After acceptance for publication, data will be available online indefinitely
To whom data/document is available
Academic and research institutes only
Under which criteria data/document could be used
For research, academic and teaching purposes only
From where data/document is obtainable
Will be available online through google drive
What processes are involved for a request to access data/document
A written request to the primary author and the institute training branch and after acceptance and permission data would be made available in the next 5 working days and a temporary google drive link will be shared to download the data in the next one week
Comments