

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 PaO₂/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

Country

Pakistan

Phone

+92 300 2509354

Email address

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 PaO₂/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

Positive 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

PaO₂/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

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Email

alijiwani512@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Ali Aftab

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City

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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

Latest degree

Specialist

Other areas of specialty/work

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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