

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Alternate use of intermittent high flow nasal cannula (HFNC) and noninvasive ventilation (NIV) on the improvement of ventilation status of patients in intensive care units.

Protocol summary

Study aim

Achieving a protocol for the use of high-flow oxygen through the nose (HFNC) and non-invasive ventilation (NIV) in icu patients.

Design

Clinical trial, community-based and pragmatic, factorial group, not blinded.

Settings and conduct

This study was conducted in the Masih Daneshvari Hospital, Mashhad, Iran. Patients requiring high-flow oxygenation were included in the study. This study will continue for six months and will be available to patients for intermittent and, if necessary, NIV and HFLN will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients have an indication of Oxygenation high and non-invasive flow, Age more than 18
Exclusion criteria: NHFL patient intolerance, Advanced cancer patients, Advanced ESRD patients, Patients with pericardial effusion.

Intervention groups

150 patients alternating in the group receiving high flow nasal cannula and non invasive ventilation.

Main outcome variables

Interpretation of arterial blood gas

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150107020592N20**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **retrospective**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

Registration date

2019-02-10, 1397/11/21

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9944

Email address

iran.criticalcare@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2019-01-29, 1397/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Alternate use of intermittent high flow nasal cannula (HFNC) and noninvasive ventilation (NIV) on the improvement of ventilation status of patients in intensive care units.

Public title

Alternate use of intermittent high flow nasal cannula (HFNC) and noninvasive ventilation (NIV) in intentionally critical care cases.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients have an indication of Oxygenation high and non-invasive flow Age more than 18

Exclusion criteria:
NHFL patient intolerarnce Advanced cancer patients
Advanced ESRD patients Patients with pericardial effusion

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Masih Daneshvari Hospital the Edjucational ,
Research and Treatment center.

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2018-08-14, 1397/05/23

Ethics committee reference number

IR.SBMU.NRITLD.REC.1397.044

Health conditions studied

1

Description of health condition studied

Pneomunia

ICD-10 code

J18.0

ICD-10 code description

Bronchopneumonia, unspecified organism

2

Description of health condition studied

Acute respiratory distress syndrome (ARDS)

ICD-10 code

J80

ICD-10 code description

Acute respiratory distress syndrome

3

Description of health condition studied

Respiratory tuberculosis

ICD-10 code

A15

ICD-10 code description

Respiratory tuberculosis

4

Description of health condition studied

Sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified organism

Primary outcomes

1

Description

Interpretation of arterial blood gas

Timepoint

Before and after

Method of measurement

Arterial blood gas

Secondary outcomes

1

Description

PCO2

Timepoint

Before and after

Method of measurement

Arterial blood gas

2

Description

PO2

Timepoint

Before and after
Method of measurement
Arterial blood gas

3

Description
Staying time in ICU
Timepoint
Before and after
Method of measurement
Assessment of patient's document

Intervention groups

1

Description
First intervention group: Patient recipients high flow nasal cannula . The selected patients receive 24 hours of HFNC 8 hours and then NIV 4 hours, again 4 hours of HFNC and then NIV 8 hours.
Category
Treatment - Devices

2

Description
Second intervention group: Patient recipients noninvasive ventilation. The selected patients receive 24 hours of NIV 8 hours and then NHFC 4 hours, again 4 hours of NIV and then NHFC 8 hours.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Dr. Seyyed Mohammadreza Hashemian
Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2912 3100
Email
iran.criticalcare@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Seyyed Mohamadreza Hashemian
Street address
SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2912 3100
Email
iran.criticalcare@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
The Edjucational , Research and Treatment center
masih daneshvari
Full name of responsible person
Seyed Mohamad Reza Hashemian
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1956944413
Phone

+98 21 2111 9279

Email

iran.criticalcare@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

The Educational , Research and Treatment center

Full name of responsible person

Seyed Mohamad Reza Hashemian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2111 9279

Email

iran.criticalcare@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

The Educational , Research and Treatment center
masih daneshvari

Full name of responsible person

Somayeh Akhavan

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2610 9512

Email

somayehakhavan30@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available