Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Efficacy of high-flow nasal cannula oxygen therapy in acute respiratory failure Compared with conventional O2 therepy

Protocol summary

Study aim
Comparison of the effect of high-flow nasal cannula oxygen therapy and nasal cannula oxygen therapy in patients with respiratory failure referred to the emergency department of Al-Zahra Hospital
Design
Single blinded clinical randomised trial
Settings and conduct
In 2020, it will be performed in the emergency room of Al-Zahra Hospital in Isfahan
Participants/Inclusion and exclusion criteria
Patients referred to the emergency room with acute respiratory failure
Intervention groups
Patients are initially treated with regular oxygen with a nasal cannulla for at least 15 minutes. if not increase in Sat O2 patients Randomly divided into two groups and They are treated with high-flow oxygen or continue with regular oxygen therapy
Main outcome variables
Increasing in blood oxygen levels

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181203041838N2**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**
Registration date
2020-12-02, 1399/09/12

Registrant information
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Mohammad Nasr-Esfahani
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date
2021-04-20, 1400/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of high-flow nasal cannula oxygen therapy in acute respiratory failure Compared with conventional O2 therepy

Public title
Efficacy of high-flow nasal cannula oxygen therapy in acute respiratory failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with acute respiratory failure
Exclusion criteria:
Unstable hemodynamic Loss of consciousness Obesity hypoventilation syndrome
Age
From **18 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
In this randomized parallel groups design, patients who fulfill the inclusion criteria are selected and by permuted block randomization of blocks size 2 randomly divided into 2 groups (intervention and control). Patients are individually assigned to 2 groups and both groups are equal in number(33 patient in each group). Random sequence generation will be done by SPSS statistical software and random sequence concealment will be done by sealed envelopes.
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
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar jerib
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Province
Isfehan
Postal code
8174673461
Approval date
2020-06-23, 1399/04/03
Ethics committee reference number
IR.MUI.MED.REC.1399.249

Health conditions studied

1

Description of health condition studied
Respiratory Failure
ICD-10 code
J96.0
ICD-10 code description
Acute respiratory failure

Primary outcomes

1

Description
increase in blood oxygen saturation level
Timepoint
Measuring the percentage increase in blood oxygen saturation level after one hour
Method of measurement
Pulse Oximetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: High pressure oxygen therapy (60 lit per min o2) In this study Patients with r espiratory failure are admitted to the emergency department. initially they are treated with ordinary oxygen with a nasal cannulla for at least 15 minutes.then in case of no recovery and no increase in Sat O2 in pulseoxymetry patients will be divided into two groups Randomly. They will be treated with high-flow oxygen(up to 60 lit per min) or continue with regular oxygen(up to 10-15 lit per min) .A group of patient used High pressure oxygen for an hour will be compared in O2 sat increse , the amount of need for intubation and the rate of ICU admission with the group that they continue with regular oxygen.(Emergency personnel have already participated in training coarse on how to work with devises.)
Category
Treatment - Devices

2

Description
Control group: nasal cannula oxygen therapy(10-15 lit per min o2)
Category
Treatment - Other

3

Description
Intervention group: BIPAP non invasive mechanical ventilation(bipap) is also used in this study to comparison approach of high flow o2 and BIPAP . a group of 33 patients with BIPAP will be intervented. they will be compared based on respiratory status , the amount of PCO2 in VBG(before and after treatment) and need to intubation or ICU addmition.
Category

Treatment - Devices

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra medical center

Full name of responsible person
Mohammad Nasr-Esfahani

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Sponsors / Funding sources

1

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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
Esfahan 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

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

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Position
assistant professor

Latest degree
Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is shared after people are not identified
When the data will become available and for how long
Start of access period from 2022
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
for research
From where data/document is obtainable
m_nasr@med.mui.ac.ir
What processes are involved for a request to access data/document
Request via email
Comments