Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effect of using suction catheter and nelaton catheter in the process of airway suctioning on the hemodynamic status of patients admitted to the intensive care unit

Protocol summary

Study aim

The main purpose of the research:Comparison of the effect of using suction catheter and nelaton catheter in the process of airway suctioning on the hemodynamic status of patients admitted to the intensive care unit The specific objective of the research: 1- Determining and comparing the average Heart Rate (HR), Respiratory Rate(RR), Oxygen Saturation (O2SAT), Diastolic Blood Pressure (DBP) ,Systolic Blood Pressure (SBP), Mean Arterial Pressure (MAP) in the group of suction catheter and Nelanon tube 1 minute before suction, then at 30 seconds, 3 and 5 minutes after suction The practical aims of the research: 1- Preventing or reducing complications caused by airway suction in patients admitted to the intensive care unit 2- Improving the hemodynamic status of patients admitted in the intensive

Design

Repeated measurres cross-over clinical trial, 44 patients, Simple randomization

Settings and conduct

Patients who meet the conditions for entering the study will enter the study after obtaining informed consent. They will be divided into two groups, A and B, by simple random, coin tossing method. Hemodynamic variables will be measured 1 minute before suction, then 30 seconds, 3 and 5 minutes after suction and side effects will be recorded.

Participants/Inclusion and exclusion criteria

GCS<8 Intubation Age 18 to 65 years Having stability in the hemodynamic range Lack of immune system defects, coagulation disorders, history of respiratory problems

Intervention groups

Group A will be suctioned with Nelaton-Nelaton-catheter-catheter sequence Group B will be suctioned with catheter-catheter-Nelaton-Nelaton sequence

Main outcome variables

Improvement of hemodynamic variables Heart Rate (HR), Respiratory Rate(RR), Oxygen Saturation (O2SAT), Diastolic Blood Pressure (DBP) ,Systolic Blood Pressure (SBP), Mean Arterial Pressure (MAP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230902059327N1**
Registration date: **2023-09-11, 1402/06/20**
Registration timing: **prospective**

Last update: **2023-09-11, 1402/06/20**
Update count: **0**

Registration date

2023-09-11, 1402/06/20

Registrant information

Name

Raziyeh Khazaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3347 7300

Email address

raz30khazaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of using suction catheter and nelaton catheter in the process of airway suctioning on the hemodynamic status of patients admitted to the intensive care unit

Public title

Effect of using suction nelaton catheter and suction catheter on the hemodynamic status

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

GCS<8 Patients with hemodynamic stability No immune, coagulation and respiratory system disorders Age range from 18 to 65 years obtaining informed consent

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method is used by throwing a coin. This method is usually used to create a random sequence in two-group trials. One of the study groups is lion and the other group is considered line, and based on the desired sample size, the same number of coins are thrown and people are randomly assigned to two groups. The person involved in the randomization program will be separate from other researchers, to reduce possible bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this one-way blind intervention, the participants are not informed which group they are in and which intervention (Nelaton tube or suction tube) started first. Each intervention is individually packaged and has an identification number. The probes are supplied in the same boxes in the same appearance and packaging. This method blinds the participants

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Rajaei Cardiovascular Medical Research Training Center

Street address

Shohada, Square Shahid Qudousi Hospital

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Postal code

6591869766

Approval date

2023-11-05, 1402/08/14

Ethics committee reference number

IR.RHC.1401.059

Health conditions studied

1

Description of health condition studied

Patients admitted to the intensive care unit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The percentage of hemodynamic index changes compared to the baseline state, in the two studied groups

Timepoint

One minute before suction, then 30 seconds, 3 and 5 minutes after suction

Method of measurement

Monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: suction of each patient 2 times with suction and 2 times with Nelaton catheter

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital in Hamedan
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Street address
Vali Asr (Aj) Ave., next to Mellat Park, Niayesh corner, Shahid Rajaei and Heart Training, Research and Treatment Center
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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
Iran University of Medical Sciences

Proportion provided by this source
20

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
Iran University of Medical Sciences
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Position
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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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts after the results are printed

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

For the purpose of presenting the article, the data will be accessible by mentioning the source and the name of the researcher.

From where data/document is obtainable

Send to the email address : raz30khazaei@gmail.com

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

Sending email with attachment, introduction letter and written request from academic or scientific institution, if approved, the data will be sent.

Comments