# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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)

**Phone**

+98 81 3347 7300

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**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

**City**

Nahavand

**Province**

Hamadan

**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**
Raziyeh Khazaei

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
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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

**Full name of responsible person**
Raziyeh Khazaei

**Position**
Masters student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursery

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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**