Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of conventional nasal intubation with ventilation during nasal intubation on hemodynamics and side effects

Protocol summary

Study aim

Determining the comparison of the complications of intubation through the conventional brouch nose with the ventilation method

Design

This study, it is a three-way blinded clinical trial in which 60 patients with eligibility conditions are selected and distributed into two groups of 30 by random assignment software. Sampling is done by random access sampling. The first group or control intubation is performed through the nose and the second group is exposed to 100% oxygen during intubation.Phase 2 on 60patients. The rand function of Excel software was used for randomization.

Settings and conduct

The physical condition of the patient is also determined and recorded based on the ASA condition in the data collection form. On the day of surgery, the patients are examined and checked for the condition of the airway in order to intubate according to the Malampati criteria. Patients will not receive any anesthetic before entering the operating room. After entering the operating room, the patients are monitored including ECG, blood pressure and pulse oximetry, and vital signs including blood pressure, MAP, heart rate and oxygen saturation percentage are recorded. In both groups, intubation was performed by an experienced anesthesiologist. And the hemodynamic changes are registered by an anesthesiologist who is not involved in the study.

Participants/Inclusion and exclusion criteria

1. First and second class physical condition patients ASAI , ASAII 2. Age over 18 years 3. BMI less than 35 Non-Inclusion criteria: 1- Any anatomical disorder in the passage of the tube 2- Severe deviation of the septum

Intervention groups

In the control group, the usual procedure of intubation is performed through the nose. In the intervention group, 100% oxygen is connected to the tracheal tube.

Main outcome variables

Mean blood pressure, Arterial blood saturation, Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N58**
Registration date: **2024-02-06, 1402/11/17**
Registration timing: **prospective**

Last update: **2024-02-06, 1402/11/17**
Update count: **0**

Registration date

2024-02-06, 1402/11/17

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of conventional nasal intubation with ventilation during nasal intubation on hemodynamics and side effects

Public title

A comparison of intubation through the nose using the conventional method with ventilation during intubation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA I , ASAII Body Mass Index(BMI) <35

Exclusion criteria:

Severe deviation of the septum Anatomical disorder in the passage of the tube History of frequent bleeding from the nose

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The number of 60 patients who meet the conditions for entering the study were selected and distributed into two groups of 30 people by random allocation software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After entering the operating room, the patients are not aware of which group they are placed in, and the researcher is not familiar with the names of the groups, and finally, the person who records the complications or assesses the secondary outcomes is not aware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of School of Isfahan University of Medical Sciences

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Hezar Jarib Ave

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Approval date

2024-01-13, 1402/10/23

Ethics committee reference number

IR.MUI.MED.REC.1402.386

Health conditions studied

1

Description of health condition studied

nose bleeding

ICD-10 code

R04.0

ICD-10 code description

Epistaxis

Primary outcomes

1

Description

Mean Arterial Pressure

Timepoint

(before the start of the intervention) and minutes 1, 3 and 5

Method of measurement

Non Invasive Blood Pressure

Secondary outcomes

1

Description

nose bleeding

Timepoint

Passing the tube into the trachea after passing through the nose

Method of measurement

Without blood, anemic, moderate and high

Intervention groups

1

Description

Intervention group: In order for hypoxia not to occur during the passage of the tracheal tube, the intervention group connected 100% oxygen to the connection of the

tracheal tube by connecting a piece called "Way-like" in the respiratory circuit of the anesthesia machine, thus reducing the arterial oxygen saturation during the passage of the tracheal tube. We prevent.

Category

Prevention

2

Description

Control group: In the control group, conventional method because tracheal tube passage takes time, so there is a possibility of reducing the oxygen saturation of arterial blood, and if the pulse oximetry number is less than 89%, the patient may suffer from oxygen deficiency within 5 to 10 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani hospital

Full name of responsible person
Akram Hemati

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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
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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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Position
Associate professor

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable