Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of selecting right or left nostril for nasotracheal intubation on incidence of complications in patient candidate for maxillofacial surgery

Protocol summary

Study aim

Comparison the effect of selecting right or left nostril for nasotracheal intubation on incidence of complications in patient candidate for maxillofacial surgery

Design

Clinical trial without a control group, with parallel, blinded, randomized groups

Settings and conduct

First, surgery is performed by alternately closing the open left and right nostrils, and nasotracheal intubation is routinely performed after induction of anesthesia. If the openness of the left and right nostrils is similar, one is performed through intubation through the left or right nostrils. The nostrils used by all patients will be recorded in their case file and a special form for each patient. Then the incidence of epistaxis, severity of bleeding in the area, incidence of intubation failure, incidence of concussion fracture, and mean duration of intubation in each patient will be recorded and recorded in a patient-specific form.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 15-70 years; Candidate for elective maxillofacial surgery under general anesthesia; Lack of sensitivity to left or right nostrils; ASA One and Two; No history of snoring or sleep apnea; Lack of previous nasal diseases such as trauma, surgery, obstruction and bleeding; Absence of coagulation disorders; Not taking medications that increase the risk of bleeding; No history of hypertension; Absence of obesity (BMI> 30); Exclusion criteria: Unable to perform nasal intubation; Any change in the intubation technique; Doubt about Konka fracture

Intervention groups

We have two intervention groups. The first group of those using the left nostril for nasotracheal intubation and the second group those using the right nostril for nasotracheal intubation

Main outcome variables

Incidence of epistaxis; severity of hemorrhage in the area; incidence of intubation failure; incidence of concussion fracture; mean duration of intubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N9**
Registration date: **2019-08-29, 1398/06/07**
Registration timing: **prospective**

Last update: **2019-08-29, 1398/06/07**
Update count: **0**

Registration date

2019-08-29, 1398/06/07

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

hamidshetabi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of selecting right or left nostril for nasotracheal intubation on incidence of complications in patient candidate for maxillofacial surgery

Public title
Comparison the effect of selecting right or left nostril for nasotracheal intubation on incidence of complications in patient candidate for maxillofacial surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 15-70 years Candidate for elective maxillofacial surgery under general anesthesia Lack of sensitivity to left or right nostrils ASA One and Two No history of snoring or sleep apnea Lack of previous nasal diseases such as trauma, surgery, obstruction and bleeding Absence of coagulation disorders Not taking medications that increase the risk of bleeding No history of hypertension Absence of obesity (BMI> 30)
Exclusion criteria:
Unable to perform nasal intubation Any change in the intubation technique Doubt about Konka fracture
Age
From **15 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Not randomized
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
Ethics committee of Isfahan Universiti of Medical Sciences
Street address
Feiz Hospital . Modares st
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2018-12-15, 1397/09/24
Ethics committee reference number
IR.MUI.MED.REC.1397.306

Health conditions studied

1

Description of health condition studied
Maxillofacial Surgery
ICD-10 code
ICD-10 code description
maxillo

Primary outcomes

1

Description
Incidence of epistaxis
Timepoint
After surgery
Method of measurement
Observation

2

Description
severity of hemorrhage in the area
Timepoint
After surgery
Method of measurement
Examination

3

Description
incidence of intubation failure
Timepoint
After surgery
Method of measurement
Observation

4

Description
incidence of concussion fracture
Timepoint
After surgery
Method of measurement
Observation

5

Description
mean duration of intubation
Timepoint
Before surgery
Method of measurement
File

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: using the left nostril for nasotracheal intubation
Category
Diagnosis

2

Description
Intervention group: using the right nostril for nasotracheal intubation
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra hospital
Full name of responsible person
Hamidreza Shetabi
Street address
Sofe Blvd, Isfahan Province, Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaqayeq Haghjoo javanmard
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Hizar jarib BLVD, Isfahan University of Medical Sciences and Health Services - Deputy of Research and Technology of the University
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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
Hamidreza Shetabi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Assistant Professor

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Person responsible for updating data

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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
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
No - There is not 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
Information about the main outcome can be shared.

When the data will become available and for how long
Start the access period 4 months after publishing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Use data to complete clinical trial studies

From where data/document is obtainable
Al-Zahra hospital

What processes are involved for a request to access data/document
After the investigation of researcher request and presentation of required documents will be accessible.

Comments