

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 Konkra 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

AgeFrom **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

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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

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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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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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Latest degree

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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