# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

26 Jun 2026

## Comparison of the severity of epistaxis between the finger guided and conventional technique of nasotracheal intubation in patients undergoing maxillofacial surgeries

## Protocol summary

**Study aim**
Determination of the severity of epistaxis in nasal endotracheal intubation with the help of finger guidance in the nasopharynx by endotracheal intubation in patients undergoing maxillofacial surgery

**Design**
This study is a double-blind randomized clinical trial performed on 68 patients undergoing maxillofacial surgery. Patients were randomly assigned to two groups using random allocation software.

**Settings and conduct**
In this study, the patient and the data collector were unaware of the study grouping The place of study is in Al-Zahra Hospital

**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 was to guide the tube blind forward until the endotracheal tube was seen in the pharyngeal area following direct laryngoscopy with a Macintosh laryngoscope. In the second group, after the finger of the non-dominant hand enters the mouth and then continues to the path to the back of the soft palate in the nasopharynx, move the endotracheal tube forward after contacting the tip of the endotracheal tube with the fingertip. The path of the endotracheal tube was done with the help of finger guidance and slowly until the endotracheal tube enters the space of the oropharynx.

**Main outcome variables**
Epistaxis

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180416039326N15**
Registration date: **2020-09-21, 1399/06/31**
Registration timing: **retrospective**

Last update: **2020-09-21, 1399/06/31**
Update count: **0**

**Registration date**
2020-09-21, 1399/06/31

**Registrant information**

**Name**
Hamidreza Shetabi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-04-21, 1397/02/01

**Expected recruitment end date**
2019-04-21, 1398/02/01

**Actual recruitment start date**
2019-01-05, 1397/10/15

**Actual recruitment end date**
2019-08-25, 1398/06/03
**Trial completion date**
2019-08-27, 1398/06/05

**Scientific title**
Comparison of the severity of epistaxis between the finger guided and conventional technique of nasotracheal intubation in patients undergoing maxillofacial surgeries

**Public title**
Comparison of epistaxis in nasal tracheal intubation With finger guidance and conventional method
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Candidate for elective maxillofacial surgery under general anesthesia ASA One and Two Informed consent to participate in the study Age: 16 to 65 years old
**Exclusion criteria:**
History of bleeding disorders History of nasopharyngeal masses History of head, face and fracture trauma of the nose and cheekbones Taking any anticoagulant History of any surgery or manipulation of the nose
**Age**
From **16 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**
Target sample size: **90**
Actual sample size reached: **68**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients who entered the study were randomly divided into two groups using computer software (Random allocation software).
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The person who performed the intubation had no role in gathering information. The person who assessing intubation complications and observer who collecting information were unaware of study groups
**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**
Sefa Boulevard
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174675731
**Approval date**
2017-06-10, 1396/03/20
**Ethics committee reference number**
IR.MUI.REC.1396.3.558

## Health conditions studied

### 1

**Description of health condition studied**
Epistaxis
**ICD-10 code**
R04.0
**ICD-10 code description**
Epistaxis

## Primary outcomes

### 1

**Description**
The severity of bleeding in the throat
**Timepoint**
After intubation through the nose
**Method of measurement**
See the throat

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: The dominant or more open nostril (Patent) was selected by alternating finger pressure on the left and right nasal fins and asking the patient to take a slow breath. Then nasal tube number 7 in women and number 7.5 in men were used for intubation. The endotracheal tube was then inserted through the dominant (more open) nostril and directed to the pharynx. In the first group, the tube was guided blindly forward until the endotracheal tube was seen in the pharyngeal area following direct laryngoscopy with a

Macintosh laryngoscope.

**Category**

Prevention

**2**

**Description**

Intervention group: In the second group, after the finger of the non-dominant hand enters the mouth and then continues to the back of the soft palate in the nasopharynx, We move the endotracheal tube forward So that after the tip of the endotracheal tube comes in contact with the tip of the finger, the end of the endotracheal tube path is guided by the finger and slowly until the endotracheal tube enters the oropharyngeal space. Then the endotracheal tube is guided to the endotracheal and if the accuracy of the intubation is ensured, the tube is fixed.

**Category**

Prevention

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Alzahra Hospital

**Full name of responsible person**
Hamidreza Shetabi

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Al-Zahra Hospital, Sofe Boulevard

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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**
Associate professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

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

**When the data will become available and for how long**
Access period starts 6 months after the results are published

**To whom data/document is available**
Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**
Use data to complete clinical trials

**From where data/document is obtainable**
Al-Zahra hospital

**What processes are involved for a request to access data/document**
By examining the researcher's request and providing sufficient documentation of her research and the reason for using the data can be provided.

**Comments**