

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Pre-emptive Epinephrine Nebulization Prior to Nasotracheal Intubation for Mandibular Fracture Fixation Surgeries

Protocol summary

Study aim

This study aimed to highlight the role of preoperative usage of epinephrine 1:1000 combined with lidocaine as nebulization session before induction of anesthesia in patients with isolated mandibular fracture undergoing elective fixation with nasotracheal intubation.

Design

prospective, randomized, single blinded, controlled trial
single center, parallel 2 groups

Settings and conduct

This randomised, prospective study performed in Ain shams university hospitals over 126 Patients ASA I and ASA II, trauma patients who suffered isolated mandibular fractures and necessitated nasal intubation during general anesthesia. The patients were randomly assigned to one of two equal groups: nasal Lidocaine drops followed by Oxymetazoline nasal drops group (OL) or Epinephrine mixed with Lidocaine as nebulization session (EL) group. An anesthesiologist not sharing in the study performed the nasal intubation.

Participants/Inclusion and exclusion criteria

Cases with American Society of Anesthesiologists (ASA) classes I and II, scheduled for elective oral isolated mandibular fracture open reduction surgeries requiring NTI, were selected. Patients with nasal abnormality and using some medications interfering with the study were excluded

Intervention groups

Group (EL) (63 patients) received a session of nebulization in the pre-induction area, consisting of 1 ml epinephrine (1:1000, 1 mg added to 9 ml of normal saline, then 1 ml of that put in nebulization cup + 2 ml lidocaine 2%), nebulized prior to the induction of anesthesia. Group OL (63 patients): These patients received five drops of lidocaine hydrochloride using a prefilled dropper, followed by six drops of hydrochloride Oxymetazoline (Otrivin adult nasal drops 0.1%, in each nostril in the pre-induction room just before the induction of anesthesia.

Main outcome variables

incidence of epistaxis during the intubation and its effect on intubation time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221226056933N1**

Registration date: **2023-02-10, 1401/11/21**

Registration timing: **retrospective**

Last update: **2023-02-10, 1401/11/21**

Update count: **0**

Registration date

2023-02-10, 1401/11/21

Registrant information

Name

Sabah Ayoub

Name of organization / entity

Ain Shams University

Country

Egypt

Phone

+20 2 24346062

Email address

sabah.nageeb@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-01, 1400/06/10

Expected recruitment end date

2022-05-01, 1401/02/11

Actual recruitment start date

2021-09-01, 1400/06/10

Actual recruitment end date

2022-04-30, 1401/02/10

Trial completion date

2022-09-30, 1401/07/08

Scientific title

Pre-emptive Epinephrine Nebulization Prior to Nasotracheal Intubation for Mandibular Fracture Fixation Surgeries

Public title

Pre-emptive Epinephrine Nebulization Prior to Nasotracheal Intubation for Mandibular Fracture Fixation Surgeries: Dose it Really Differs? a Randomized Controlled Study

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

- Cases with American Society of Anesthesiologists (ASA) classes I and II.
- Patients scheduled for elective oral isolated mandibular fracture fixation requiring nasotracheal intubation.

Exclusion criteria:

- Nasal abnormality history (such as polyp, surgery or nasal trauma).
- Frequent epistaxis history.
- Patients suffering from valvular heart disease, hypertension, ischemic heart disease or arrhythmias.
- Patients using drugs (anticoagulation therapy, non-steroidal anti-inflammatory drugs, and oral decongestant).
- Patients receiving medications known to alter the parameters under investigation including β -blockers, calcium channel blockers, or vasodilators.
- Patients known to have hypersensitivity to medications used in this study.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider

Sample size

Target sample size: **126**

Actual sample size reached: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using a computer-generated randomization sequence and allocation concealment to be maintained all through the time of procedure, by using opaque, numbered, and sealed envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The investigators are aware of the given medication, Only the anesthesiologist who performed the nasal intubation was not aware of the given medication.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

RESEARCH ETHICS COMMITTEE (REC) Board

Affiliation: Ain Shams University

Street address

!31- Ramsis street

City

Abbasia- Cairo-Egypt

Postal code

7539

Approval date

2064-01-06, 1442/10/16

Ethics committee reference number

FMASU R 132/2021

Health conditions studied**1****Description of health condition studied**

Nasal Bleeding - mandibular fracture fixation surgeries

ICD-10 code

R04.0

ICD-10 code description

Epistaxis

Primary outcomes**1****Description**

estimate the degree of epistaxis during nasal intubation

Timepoint

after the intervention

Method of measurement

Epistaxis degrees during intubation is classified to 4 degrees 1-No bleeding means No interference with the laryngoscopic view, 2- minimal bleeding means Just blood-tinged ETT but no blood on the vocal cords or mouth floor, 3-moderate bleeding means Blood on the vocal cords and mouth floor which Interferes with the laryngoscopic view, but is easy to confirm the laryngeal structure, 4-severe bleeding means Blood on the vocal cords and mouth floor Hard to visualize the laryngeal structure without suction because of bleeding

Secondary outcomes

1

Description

1. intraoperative analgesia

Timepoint

whole intraoperative time

Method of measurement

intraoperative analgesia is indicated by intraoperative hemodynamics and total intraoperative fentanyl consumption

2

Description

2. intraoperative blood loss from surgical field

Timepoint

intraoperative time

Method of measurement

intraoperative volume of blood loss was estimated

Intervention groups

1

Description

Intervention group: Active Comparator: Group (EL) Epinephrine and Lidocaine group (EL) (63 patients) received a session of nebulization in the pre-induction area, consisting of 1 ml epinephrine (1:1000 Martindale Pharma, an Ethypharm Group Company, ampoule 1 mg added to 9 ml of normal saline, then 1 ml of that put in nebulization cup + 2 ml lidocaine 2%), nebulized prior to the induction of anesthesia. (63 patients) received a session of nebulization in the pre-induction area, consisting of 1 ml epinephrine (1:1000 Martindale Pharma, an Ethypharm Group Company, ampoule 1 mg added to 9 ml of normal saline, then 1 ml of that put in nebulization cup + 2 ml lidocaine 2%), nebulized prior to the induction of anesthesia.

Category

Prevention

2

Description

Intervention group: Oxymetazoline and lidocaine group (OL) (63 patients): These patients received five drops of lidocaine hydrochloride (Xylocaine 2%, 20 mg/ml; Active Comparator: Group (OL) Oxymetazoline and lidocaine group (OL) (63 patients): These patients received five drops of lidocaine hydrochloride (Xylocaine 2%, 20 mg/ml; AstraZeneca, London, UK) using a prefilled dropper, followed by six drops of hydrochloride Oxymetazoline (Otrivin adult nasal drops 0.1%, 10 ml of 1 mg/ml; Novartis Consumer Health, UK Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK) in each nostril in the pre-induction room just before the induction of anesthesia

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals of Ain Shams University

Full name of responsible person

Sabah Naguib Barsoom Ayoub

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ain Shams University

Full name of responsible person

RESEARCH ETHICS COMMITTEE (REC) Board

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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

Ain Shams University

Proportion provided by this source

1

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

Ain Shams University

Full name of responsible person

Sabah Naguib Barsoom Ayoub

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

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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

Pre-emptive Epinephrine Nebulization Prior to Nasotracheal Intubation for Mandibular Fracture Fixation Surgeries:Dose it Really Differs? a Randomized Controlled Study

When the data will become available and for how long

after 6 months for 1 year

To whom data/document is available

For people working in anesthesia field

Under which criteria data/document could be used

as citation

From where data/document is obtainable

sabah.nageeb@yahoo.com

What processes are involved for a request to access data/document

through the official email within one week , can share data

Comments