Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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 bleading 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) Epinepherine and Lidocaone groupGroup (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 groupGroup OL (63 patients): These patients received five drops of lidocaine hydrochloride (Xylocaine 2%, 20 mg/ml;Active Comparator: Group(OL) Oxymetazoline and lidocaine groupGroup 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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131- Ramsis street
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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
Affiliation: Ain Shams University
Street address
131- Ramsis street
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FMASU@med.asu.edu.eg
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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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