Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of oro-tracheal (classical) and naso-tracheal (blindly) intubation methods on ease of airway management and hemodynamic stability during intubation of acute burn patients with difficult airway condition

Protocol summary

Study aim

The ease of intubation and Hemodynamic stability during difficult airway management is compared with oral and nasal intubation in patients with acute burns.

Design

Clinical trial, with single-blind, randomized groups, on 20 patients.Random number table was used for randomization.

Settings and conduct

Many patients with acute burns develop progressive airway obstruction and respiratory distress due to severe head, face, and upper extremity injuries. Tracheal intubation after local anesthesia in the patient's throat can be performed blindly with only mild sedation.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1) Patients aged 18 to 57 years with acute head and face burns and are candidates for emergency intubation due to progressive airway obstruction or severe hypoxia (SPaO2 <90%) 2) They have a problem airway (Malampati Ⅲ and Ⅳ). exclusion criteria: 1) The patient is not breathing 2) Severe restlessness 3) Shock 4) Patient with a history of previous underlying disease (severe liver disease, severe hemodynamic disorder and disease with coagulation disorder) 5) Hypertension 6) Taking anticoagulants 7) Trauma to the head, face and neck 8) Have rhinoplasty

Intervention groups

Group O: Group O patients are intubated according to the protocol after administration of midazolam , fentanyl , ketamine , and laryngoscopy. Group N: Patients in group N are pre-oxygenated and intubated after administration of topical lidocaine in the pharynx..

Main outcome variables

* Airway management status * Hemodynamic stability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140421017372N2**
Registration date: **2022-02-01, 1400/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-01, 1400/11/12**
Update count: **0**

Registration date

2022-02-01, 1400/11/12

Registrant information

Name

Reza Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2249 7975

Email address

salehi.r@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of oro-tracheal (classical) and naso-tracheal (blindly) intubation methods on ease of airway management and hemodynamic stability during intubation of acute burn patients with difficult airway condition

Public title
Comparison of the effect of endotracheal intubation through the mouth and nose on the ease of intubation and cardiovascular status during intubation of patients with acute burns with severe airway obstruction.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with acute burns of the head and face Patients with progressive airway obstruction or severe hypoxia are candidates for emergency intubation difficult airway (Mallampati Ⅲ and Ⅳ) Patients should have spontaneous breathing

Exclusion criteria:
Patient without spontaneous breathing Patient with a history of underlying heart disease (severe liver disease, severe hemodynamic disorder and coagulation disorder) Hypertension Taking anticoagulants Trauma to the head, face and neck nose surgery and nose anomaly severe restlessness

Age
From **18 years** old to **57 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Block type is used for limited randomization. In this way, patients are divided into two groups by block randomization. Assignment Sequences Using Web Systems Produced by www-sealedenvelope.com/. In order to create an allocation sequence in this system, the number of subjects in each block was determined as 2 people. Thus, the letter o was created for the group that is intubated orally and the N group was created for the group that is intubated nasally, and finally, by confirming the allocation sequence in the above system, 10 allocation sequences were created for 20 samples by combining the letters N and O. Then the cards containing the blocks are placed inside the opaque envelope, thus concealing the allocation is also considered and observed.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, patients are unaware of the method to be used in intubation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Tehran, Hemmat Highway next to Milad Tower

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2021-01-03, 1399/10/14

Ethics committee reference number
IR.IUMS.FMD.REC.1399.545

Health conditions studied

1

Description of health condition studied
Acute head and neck burns

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Number of endotracheal tubes consumed

Timepoint
First entry - during intubation - 5 minutes after intubation

Method of measurement
Counting by the nurse

2

Description
blood pressure

Timepoint
First entry - during intubation - 5 minutes after intubation

Method of measurement
Mercury barometer

3

Description
Respiratory Rate
Timepoint
First entry - during intubation - 5 minutes after intubation
Method of measurement
Pulse oximetry

4

Description
Arterial oxygen saturation level
Timepoint
First entry - during intubation - 5 minutes after intubation
Method of measurement
Pulse oximetry

5

Description
heart rate
Timepoint
First entry - during intubation - 5 minutes after intubation
Method of measurement
Chest lead connected to the monitor

6

Description
Number of intubation attempts
Timepoint
First entry - during intubation - 5 minutes after intubation
Method of measurement
Counting with the help of a nurse

7

Description
Apnea and cardiac arrest
Timepoint
First entry - during intubation - 5 minutes after intubation
Method of measurement
by nurse

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in group N are initially pre-oxygenated for 5 minutes and after administering a total of 6 puffs of 10% topical lidocaine in the nasopharynx, uro and hypopharynx, pass the endotracheal tube through the nostrils and intubate the patient with the help of breathing sound. We do.
Category
Treatment - Drugs

2

Description
Control group: Patients in group O are intubated according to the usual method after administration of midazolam (0.03 mg / kg), fentanyl (2 /g / kg), ketamine (1.5 kg / min) and laryngoscopy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Motehari Burn Hospital
Full name of responsible person
Dr Reza Salehi
Street address
Motehari Burn Hospital, Shahid Yasemi St., Vali-e Asr Str, Vanak Sq.
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
PR@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Naser Bakht
Street address
Iran University of Medical Sciences ,Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
PR@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Shayan Sanati
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Av, Tehran, IRAN
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 8880 4527
Fax
Email
shayansanati@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Salehi
Position
assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Burn Motehari Hospital, Yasemi St., Vali-Asr St.,Vanak Sq.
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8877 0031
Fax
Email
salehi.r@iums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Salehi
Position
assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Burn Motehari Hospital, Yasemi St., Vali-Asr St.,Vanak Sq.
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8877 0031
Fax
Email
salehi.r@iums.ac.ir
Web page address

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
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only part of the data, such as information about the main outcome, can be shared.
When the data will become available and for how

long

Access period starts 3 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data of this study can only be used in the field of research.

From where data/document is obtainable

Refer to Dr. Reza Salehi.

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

After sending the request and approval by Dr. Salehi et al., The data will be sent.

Comments