

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 (Mallampati 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 addressHazrate Rasool 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**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 addressBurn 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 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 addressBurn Motehari Hospital, Yasemi St., Vali-Asr St., Vanak
Sq.**City**

Tehran

Province

Tehran

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 PlanUndecided - 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 CodeUndecided - 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