

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison between two methods of emergency rapid sequence intubations (with and without apneic oxygenation) regarding arterial oxygen desaturation during tube placement

Protocol summary

Study aim

To elucidate the possible effect of apneic oxygenation on delaying the arterial oxygen desaturation during laryngoscopy for rapid sequence intubation in the emergency department

Design

Randomised, non-blinded, parallel group without concealment, including two groups with 30 patients in each group.

Settings and conduct

This study will be performed in Bahonar Academic Hospital, an urban level 2 trauma center located in Kerman, Iran. Rapid sequence intubation is performed by the most skilled patient available in the emergency department (senior resident of emergency medicine or the attending physician of emergency medicine), with the researcher observing the condition and documenting the data. Patients who are not assigned to the intervention are intubated using the standard protocol (pre-oxygenation, pre-treatment, induction,) and those who are assigned to apneic oxygenation receive oxygen in addition to the standard of care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Trauma patients over 18 years of age needing emergency orotracheal intubation. Exclusion criteria: Patients who are not candidates for rapid sequence intubation; Patients who remain hypoxic (arterial oxygen saturation < 95%) despite adequate pre-oxygenation; Patients whose arterial oxygen saturation can not be traced using pulse oxymetry for any reason (like hemodynamic shock, etc.)

Intervention groups

Our intervention includes oxygenation via a nasal cannula with oxygen flow rate of 10 L/min during the apneic stage of rapid sequence intubation, during which laryngoscopy is performed and is followed by tube placement. The current standard of rapid sequence

intubation does not include apneic oxygenation during laryngoscopy.

Main outcome variables

Arterial oxygen saturation immediately after the tube placement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131226015941N6**

Registration date: **2018-07-27, 1397/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-27, 1397/05/05**

Update count: **0**

Registration date

2018-07-27, 1397/05/05

Registrant information

Name

Amirhossein Mirafzal

Name of organization / entity

Kerman University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1247 4638

Email address

mirafzal@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-11, 1397/04/20

Expected recruitment end date

2018-10-02, 1397/07/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison between two methods of emergency rapid sequence intubations (with and without apneic oxygenation) regarding arterial oxygen desaturation during tube placement

Public title
Oxygenation via nasal cannula during laryngoscopy by the emergency physicians: A comparison between the users and the non-users

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Trauma patients over 18 years of age needing emergency orotracheal intubation in the emergency department
Exclusion criteria:
Patients who are not candidates of rapid sequence intubation (RSI) for any reason Patients who remain hypoxic (arterial oxygen saturation<95%) despite adequate pre-oxygenation Patients whose arterial oxygen saturation could not be traced using pulse oxymeter (for any reason like hemodynamic shock, etc.)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
We use simple randomization using random numbers table. Each individual is a unit for randomization. The even numbers will be assigned to group 1 (no oxygenation during laryngoscopy) and the odd numbers will be assigned to group 2 (oxygenation via nasal cannula during laryngoscopy). There is no allocation concealment in this study.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Afzalipoor Clinical Research Center, Kerman University of Medical Sciences

Street address

Imam Khomeini Rd., next to the Bahonar University, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913911

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

IR.KMU.AH.REC.1396.2092

Health conditions studied

1

Description of health condition studied

Endotracheal intubation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Arterial oxygen saturation immediately after the endotracheal tube placement

Timepoint

Once, immediately after endotracheal tube placement

Method of measurement

Reading of pulse oxymetry

Secondary outcomes

1

Description

Time taken (in seconds) for each attempt (laryngoscopy) at intubation

Timepoint

Once at the end of each attempt

Method of measurement

Taking the time by the researcher

2

Description

Number of attempts at intubation
Timepoint
Once at the end of intubation
Method of measurement
Counting by the researcher

Intervention groups

1

Description
Control group: Standard rapid sequence intubation
Category
Treatment - Devices

2

Description
Intervention group: Standard rapid sequence intubation with added oxygenation during the apneic period (laryngoscopy)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahonar Academic Hospital
Full name of responsible person
Amirhossein Mirafzal
Street address
Gharani St., Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
mirafzal@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhty
Street address
Soamey cross, Ebne Sina st., Kerman, Iran
City
Kerman
Province
Kerman
Postal code

7616913555
Phone
+98 34 3226 3855
Email
abpardakhty@kmu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Amirhossein Mirafzal
Position
Assistant professor
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Bahonar Academic Hospital, Gharani St., Kerman
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
mirafzal@kmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Amirhossein Mirafzal
Position
Assistant Professor
Latest degree
Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Bahonar Academic Hospital, Gharani St., Kerman

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Fax**Email**

mirafzal@kmu.ac.ir

Web page address

+98 34 3223 5011

Fax**Email**

mirafzal@kmu.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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

One month after publication

To whom data/document is available

Persons with Academic positions

Under which criteria data/document could be used

Data will be sent until one month after request for the qualified person(s).

From where data/document is obtainable

Request for data can be sent via email.

(mirafzal@kmu.ac.ir- a.mirafzal@yahoo.com)

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

Data will be sent via email until one month after request

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Amirhossein Mirafzal

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Bahonar Academic Hospital, Gharani St.

City

Kerman

Province

Kerman

Postal code

7611747181

Phone