

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Sep 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 Bafonar 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)

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+98 34 1247 4638

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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

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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

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Gharani St., Kerman, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

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

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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

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Position

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Latest degree

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