Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Compare the rate of complication and successful orotracheal intubation performed with a stylet or without a stylet

Protocol summary

Study aim
The real aim of this study is Comparison of the rate of complication and successful orotracheal intubation performed with a stylet or without a stylet(for probability of stylet deletion in Endotracheal Intubation)
Design
Randomized Clinical Trial, Single blinded with parallel group
Settings and conduct
Endotracheal Intubation with direct Laryingoscopy in Emergency Department
Participants/Inclusion and exclusion criteria
Inclusion criteria; All patient beyond 18 years old who need endotracheal intubation for medical reason for example: cardiopulmonary arrest, LOC, seltic shoke, seizure, COPD, Asthma, cardiac failure, pneumonia. Traumatic Brain Injeury Exclusion criteria; 1. under 18 years old 2.history of cervical spine surgery 3.history of upper airway structural problems, laryngeal mass, 4.pregnant women
Intervention groups
one group intubated with stylet and another group intubated without use of stylet
Main outcome variables
Success rate of Intubation Complication of intubation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191210045684N1**
Registration date: **2020-01-26, 1398/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-26, 1398/11/06**
Update count: **0**
Registration date
2020-01-26, 1398/11/06

Registrant information
Name
Adel Shokouhi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-08-23, 1398/06/01
Expected recruitment end date
2020-05-19, 1399/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Compare the rate of complication and successful orotracheal intubation performed with a stylet or without a stylet

Public title
Compare the rate of complication and successful orotracheal intubation performed with a stylet or without a stylet
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Cardiopulmonary arrest Septic shoke Seizure Asthma

COPD Cardiac failure Pneumonia Trauma Traumatic Brain Injeury

Exclusion criteria:

History of cervical spine surgery History of upper airway structural problems, laryngeal mass Pregnant women

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **190**

Randomization (investigator's opinion)

Randomized

Randomization description

Before biginnig of study, Patients devided into two groups by randome numbers table; first group intubated with stylet and second group intubated without use of stylet.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient has not any awareness oo intubation method

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Mazandaran University of Medical Sciences

Street address

Jouybar threeway-Vali Asre avenue

City

Sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2019-08-19, 1398/05/28

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.072

Health conditions studied

1

Description of health condition studied

Endotracheal Intubation

ICD-10 code

T88.4

ICD-10 code description

Failed or difficult intubation

Primary outcomes

1

Description

Succession in Endotracheal Intubation

Timepoint

In the biginnig and immediately after procedure

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Endo tracheal Intubation with Stylet that used traditionally for ease of intubation and may be with some complication.

Category

Treatment - Devices

2

Description

Control group: Endo tracheal Intubation without Stylet use for prevention of potentially complication

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam KHomeini Hospital

Full name of responsible person

Dr. Misagh Shafizad

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Razi avenue

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Mazandaran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
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Position
Resident
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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
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Endotracheal Intubation

When the data will become available and for how long
One month after print of rsaults

To whom data/document is available
All of Researchers

Under which criteria data/document could be used
without limitation

From where data/document is obtainable
Sari Imam KHomeini hospital

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

Comments