

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

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

Protocol summary

2020-01-26, 1398/11/06

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 Laryngoscopy 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

Registrant information

Name

Adel Shokouhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3231 0352

Email address

adelshokouhi@yahoo.com

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

Street address

Razi avenue

City

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Province

Mazandaran

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48166-33131

Phone

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Email
ict@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran 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

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
Adel Shokouhi
Position
Resident
Latest degree
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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 results

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

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Comments