

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the hemodynamic changes following tracheal intubation with direct laryngoscopy and fiberoptic bronchoscopy and glidescope in patients with ASA Class I-II elective surgery candidates

Protocol summary

Study aim

Comparison of hemodynamic changes following tracheal intubation by three direct laryngoscopy instruments, fibropetic bronchoscope, and glidescope

Design

Clinical intervention trial with parallel, blind, randomized groups

Settings and conduct

This study, which is a randomized clinical trial, is started by a random sampling of 195 patients in three groups. The choice of these individuals is randomized using a random number table and all patients selected are in the age group of 15 to 65 years old who are admitted to the surgical department of Baqiyatallah Hospital and have ASA class I and II. Patients and researchers are blinded, but the supervisor knows how each patient has been treated. Blindness is a two-way blind.

Participants/Inclusion and exclusion criteria

Patients with difficult intubation, obesity, systemic disease such as uncontrolled hypertension, heart disease, DM, uncontrolled hyperthyroidism, hypothyroidism and patients candidate for cesarean section

Intervention groups

Group 1: Patients whose intubations are performed by direct laryngoscopy Group 2: Patients whose intubation was performed by a fibropetic bronchoscope Group three: Patients whose intubation was done by a glidescope

Main outcome variables

Determination of reduction of hemodynamic changes after intubation by fibropetic bronchoscopy in comparison with direct laryngoscopy and glideoscope

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151031024799N4**

Registration date: **2019-05-05, 1398/02/15**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-05, 1398/02/15**

Update count: **0**

Registration date

2019-05-05, 1398/02/15

Registrant information

Name

Masoud Saghafinia

Name of organization / entity

Baqiyatallah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 3207

Email address

dr_saghafi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the hemodynamic changes following tracheal intubation with direct laryngoscopy and fiberoptic bronchoscopy and glidescope in patients with ASA Class I-II elective surgery candidates		Name of ethics committee The Ethics Committee of the Baqiyatallah University of Medical Sciences	
Public title	Comparison of the hemodynamic changes following tracheal intubation	Street address	Baqiyatallah University of Medical Sciences, Tehran, Iran
Purpose	Treatment	City	Tehran
Inclusion/Exclusion criteria		Province	Tehran
Inclusion criteria:	Patients with ASA class I, II candidates for elective surgery	Postal code	1435915371
Exclusion criteria:	Patients with difficult intubation obesity uncontrolled hypertension heart disease DM uncontrolled hyperthyroidism, hypothyroidism patients candidate for cesarean section	Approval date	2017-03-05, 1395/12/15
Age	From 15 years old to 65 years old	Ethics committee reference number	ir.BMSU.REC.1395.247
Gender	Both	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	- Participant - Investigator - Outcome assessor - Data analyser	Description of health condition studied Intubation	
Sample size	Target sample size: 196	ICD-10 code O29.6	
Randomization (investigator's opinion)	Randomized	ICD-10 code description Failed or difficult intubation for anesthesia during pregnancy	
Randomization description	After entering the study and obtaining informed consent, patients will be randomly assigned to the random numbers table in three groups of 65.	Primary outcomes	
Blinding (investigator's opinion)	Double blinded	1	
Blinding description	The patient does not know which method of intubation receives; the researcher like the patient does not know which patient is in what group and which method he receives. The supervisor knows which patient gets what method.	Description Blood pressure	
Placebo	Not used	Timepoint Before and after induction and during intubation and one, three and five minutes after intubation	
Assignment	Parallel	Method of measurement Barometer cuff	
Other design features		2	
Secondary Ids	empty	Description heart rate	
Ethics committees		Timepoint Before and after induction and during intubation and one, three and five minutes after intubation	
1		Method of measurement Heart Rate Monitor	
Ethics committee		3	
		Description Arterial oxygen saturation level	
		Timepoint Before and after induction and during intubation and one, three and five minutes after intubation	
		Method of measurement Pulse Oximeter	

Secondary outcomes

1

Description

Incidence of myocardial infarction

Timepoint

At one year after surgery

Method of measurement

electrocardiogram

Intervention groups

1

Description

Intervention group1 : Patients whose intubation will be performed by a fiberoptic bronchoscope. Systolic and diastolic blood pressure and heart rate of patients are measured noninvasively, before and after induction, during intubation, and minutes after 1, 3, and 5 minutes after intubation.

Category

Treatment - Devices

2

Description

Intervention group: Patients whose intubation will be performed by a glidescope. Systolic and diastolic blood pressure and heart rate of patients are measured noninvasively, before and after induction, during intubation, and minutes after 1, 3, and 5 minutes after intubation.

Category

Treatment - Devices

3

Description

Control group: Patients whose intubation will be performed by a direct Laryngoscope . Systolic and diastolic blood pressure and heart rate of patients are measured noninvasively, before and after induction, during intubation, and minutes after 1, 3, and 5 minutes after intubation.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiyyatollah al-Azam Hospital

Full name of responsible person

Masoud Saghafinia

Street address

Molla Sadra St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8805 0435

Email

masoud.saghafinia1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr Masoud Saghafinia

Street address

Molla Sadra St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435915372

Phone

+98 21 8805 0435

Email

masoud.saghafinia1@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Masoud Saghafinia

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Baghiyyatollah al-Azam Hospital, Molla Sadra St,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8805 0435

Email

masoud.saghafinia1@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Masoud Saghafinia

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Baghiyyatollah al-Azam Hospital, Molla Sadra St,
Tehran, Iran

City

Tehran

Province

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Postal code

1435915371

Phone

+98 21 8805 0435

Email

masoud.saghafinia1@gmail.com

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Masoud Saghafinia

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Baghiyyatollah al-Azam Hospital, Molla Sadra St,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14359115371

Phone

+98 21 8805 0435

Email

masoud.saghafinia1@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total data of the participants in the study after the unidentifiable individuals can be shared.

When the data will become available and for how long

The beginning of the access period is 6 months after the publication of the results.

To whom data/document is available

Data is only available to researchers working in scientific institutions.

Under which criteria data/document could be used

Authorized people can do all the analyses that they need on the data.

From where data/document is obtainable

People can contact us by email:
masoud.saghafinia1@gmail.com

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

Individuals can receive data within one day after emailing us.

Comments