

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of successful endotracheal intubation between the "standard-method" and "Modified-ramped position"

Protocol summary

Determining the effectiveness of modified roll ramp on intubation

Study aim

Determining the effectiveness of a modified roll ramp on intubation of surgical candidates
Determining the effect of modified ramp roll on the number of attempts to successfully intubation
Determining the effect of modified ramp roll on duration of intubation
Determination and comparison of cormack lehane score in intubation of patients in the modified roll ramp group with the standard group

Design

Randomized, blind clinical trial. 112 patients were divided into two groups: case group(n = 56) and control group (n = 56). Ps:
[//www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists) will be used for randomization.

Settings and conduct

After obtaining a sampling permit, patients in the operating room of Beheshti Hospital in Qom who meet the inclusion criteria are asked for informed consent to enter the study. Then, by random sampling, patients are divided into control and intervention groups. Intubation by An anesthesiologist is performed and the data is prepared through a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 15 to 80 years Mallampati patients score II-IV Patients who will undergo non-emergency general anesthesia Having informed consent to participate in the study
Criteria for not entering: Patients undergoing local or spinal anesthesia Patient dissatisfaction at any stage of the research
Restriction on positioning in modified RAMP position
History of any disease that causes instability of the cervical spine
Patients with limited neck extension and flexion movement
Patients with large neck masses

Intervention groups

After random sampling, in the intervention group ,patient supine on a modified RAMP as a trapezoidal device, and intubation is performed by an anesthesiologist.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220511054817N1**

Registration date: **2022-05-22, 1401/03/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-22, 1401/03/01**

Update count: **0**

Registration date

2022-05-22, 1401/03/01

Registrant information

Name

Sourena Rezvani dehaghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2295 2912

Email address

sourena1374@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-15, 1401/02/25

Expected recruitment end date

2022-06-15, 1401/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of successful endotracheal intubation between the " standard-method " and " Modified-ramped position"

Public title

Comparison of successful endotracheal intubation between the " standard-method " and " Modified-ramped position"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged between 15 and 80 years Patients with Malampati Score 2 to 4 Patients who will undergo non-emergency general anesthesia Having informed consent to participate in the study

Exclusion criteria:

Patients undergoing local or spinal anesthesia Patient dissatisfaction at any stage of the research Restriction of position in the modified ramp position History of any disease that causes instability of the cervical spine Patients with limited neck extension and flexion movement Patients with large neck masses

Age

From **15 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are easily entered into the study and randomly assigned to intervention and control groups. The site <https://www.sealedenvelope.com/simple-randomiser/v1/lists> will be used for random allocation of samples by randomized block method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients who meet the inclusion criteria enter the study after receiving full explanations about the research and how to conduct the research and obtain informed consent.Cases are divided into two groups of case and control by random sampling method.Intubation of both intervention and control groups is performed by an anesthesiologist and the data is collected and completed by an operating room technician who is not aware of the intervention and control group in the research through a checklist prepared by the researcher.Data analysis is performed by a statistical expert who is not aware of the

intervention and control group in the research.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Biomedical Research, Qom University of Medical Sciences

Street address

No. 20, Valiasr Ave., artesh Blvd., aqdasiyeh

City

Tehran

Province

Tehran

Postal code

1694733415

Approval date

2022-05-10, 1401/02/20

Ethics committee reference number

IR.MUQ.REC.1401.010

Health conditions studied**1****Description of health condition studied**

Intubation of surgical candidate patients

ICD-10 code

T88.4

ICD-10 code description

Failed or difficult intubation

Primary outcomes**1****Description**

Duration of intubation

Timepoint

At the beginning of the study

Method of measurement

Measuring intubation time in seconds (with the help of a blind person to the type of intervention)

2**Description**

Number of attempts for successful intubation

Timepoint

At the beginning of the study

Method of measurement

Counting the number of times intubation (with the help of a blind person to the type of intubation intervention)

3

Description

Patient satisfaction

Timepoint

12 hours after surgery

Method of measurement

Based on the Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group (M), the patient is placed in a supine position on a modified RAMP (a trapezoidal device with a height of 15 cm, and a length of 80 cm, with an angle of 30 degrees, which has a length of 20 cm and 80 cm).)At the entrance to the operating room, an airway evaluation is performed for patients (including Malampati score, Cormac Lehan, thyromental distance, mouth opening, and neck extension). Prior to surgery, patients will receive IV isotonic fluid. Before induction of anesthesia, conventional monitors including electrocardiogram, non-invasive blood pressure monitor and pulse oximetry will be used for evaluation. For induction of anesthesia, 1-2 mg / kg propofol, 0.1 mg / kg cis atracurium and 0.2 µg / kg sufentanil are used. Also, ventilation mask using face mask, 3 minutes before induction is done as current volume ventilation, then with tube number 7 - 7.5 - 8 by the same anesthesiologist and using Macintosh laryngoscope intubation is done. The correct position of the endotracheal tube is confirmed by capnography and after intubation, the patient returns to the standard position after 10 minutes with caution. Then, 6 to 12 hours after the operation, the patient's satisfaction is recorded based on the patient's general condition and the feeling of pain after intubation by visual analog scale.

Category

Treatment - Devices

2

Description

Control group: In the control group (S), patients are usually placed in the supine position and a pillow 10 cm high is placed under the patient's head. At the entrance to the operating room, an airway evaluation is performed for patients (including Malampati score, Cormac Lehan, thyromental distance, mouth opening, and neck extension). Prior to surgery, patients will receive IV isotonic fluid. Before induction of anesthesia, conventional monitors including electrocardiogram, non-invasive blood pressure monitor and pulse oximetry will be used for evaluation. For induction of anesthesia, 1-2

mg / kg propofol, 0.1 mg / kg cis atracurium and 0.2 µg / kg sufentanil are used. Also, ventilation mask using face mask, 3 minutes before induction is done as current volume ventilation, then with tube number 7 - 7.5 - 8 by the same anesthesiologist and using Macintosh laryngoscope intubation is done. The correct position of the endotracheal tube is confirmed by capnography and after intubation, the patient returns to the standard position after 10 minutes with caution. Then, 6 to 12 hours after the operation, the patient's satisfaction is recorded based on the patient's general condition and the feeling of pain after intubation by visual analog scale.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Educational and Medical Center

Full name of responsible person

Sourena Rezvani deaghani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Alireza Koochpaei

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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
Ghoum 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
Ghoum University of Medical Sciences
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Position
medical intern
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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