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

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 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
Determining the effectiveness of modified roll ramp on intubation

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: n 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 dehaghani
Street address
No. 20, Valiasr Ave., artesh Blvd., aqdasiyeh
City
Tehran
Province
Tehran
Postal code
1694733415
Phone
+98 21 2295 2912
Email
Sourena1374@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Alireza Koohpaei
Street address
No. 83, Shahod lotfi niyasar Ave., Safashahr Blvd
City
qom
Province
Ghoum
Postal code
93456-37169
Phone
+98 25 3285 2720
Email
research@muq.ac.ir
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

Full name of responsible person

Sourena Rezvani dehaghani

Position

medical intern

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

No. 20, Valiasr Ave., Aqdasiyeh

City

Tehran

Province

Tehran

Postal code

1694733415

Phone

+98 21 2295 2912

Email

Sourena1374@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Sourena Rezvani Dehaghani

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

No. 20, Valiasr Ave.,Artesh Blvd., Aqdasiyeh

City

Tehran

Province

Tehran

Postal code

1694733415

Phone

+98 21 2295 2912

Email

Sourena1374@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Sourena Rezvani dehaghani

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

No 20 , Valiasr Ave , Artesh Blv , Aqdasiyeh

City

Tehran

Province

Tehran

Postal code

1694733415

Phone

009822952912

Email

Sourena1374@gmail.com

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