

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the efficiency of The Combined Method of Nasogastric Tube Insertion with The Conventional Method in Unconscious Intubated Patients

Protocol summary

Study aim

Evaluation of the effectiveness of the combined method of nasogastric intubation in unconsciousness and intubated patients compared to the conventional method

Design

Clinical trial with two groups, which includes control (conventional method) and intervention (combined method), the number required for each group is 30 people (60 in total). The patients were randomly divided into 2 control and intervention groups, and the study was one side blinded, and a table of numbers was used for randomization.

Settings and conduct

Sampels will be taken in Hashminejad and Imam Reza emergency departments Mashhad. A one side blinded study with only patients being blinded.

Participants/Inclusion and exclusion criteria

Intubated and unconsciousness patients who need a nasogastric tube The person is at least 18 years old and does not have active bleeding, coagulation problems, or esophageal varices

Intervention groups

NG tube placement with new combined method

Main outcome variables

success rate ; NG tube placement time; Immediate complications of Ng placement; Number of attempts for NG placement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230623058561N1**

Registration date: **2023-11-07, 1402/08/16**

Registration timing: **prospective**

Last update: **2023-11-07, 1402/08/16**

Update count: **0**

Registration date

2023-11-07, 1402/08/16

Registrant information

Name

saeed razghandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 938 728 2429

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficiency of The Combined Method of Nasogastric Tube Insertion with The Conventional Method in Unconscious Intubated Patients

Public title

New combined method for Ng insertion in Unconscious Intubated Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 Order of physician for Ng tube insertion age more than 18 patients must be intubated patient must be unconsciousness and not cooperating (GCS<9 or Ras < -2 or ACVPU = U) Dose not have current bleeding Dose not have any fractures in base skull Dose not have esophageal varices Not having recent surgeries in esophageal area

Exclusion criteria:
 Unstable hemodynamics when patient need resuscitation Narrowing or deviation of nostrils (The NG tube dose not go forward in esophagus by nostrils) Bradycardia (HR <60)

Age
 From 18 years old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: 60

Randomization (investigator's opinion)
 Randomized

Randomization description
 1. Selection of a foreigner 2. Using the table of random numbers according to the sample size 3. Odd numbers are assigned to the control group and even numbers are assigned to the intervention group

Blinding (investigator's opinion)
 Single blinded

Blinding description
 People participating in the research and under the study are blinded.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics committee of Mashad University of Medical Sciences

Street address
 15 Abolkheir Ave. 17 North motahari Blvd. 3Block Mashad city

City
 Mashad

Province
 Razavi Khorasan

Postal code
 9193754688

Approval date
 2023-10-28, 1402/08/06

Ethics committee reference number
 IR.MUMS.NURSE.REC.1402.088

Health conditions studied

1

Description of health condition studied
 NG tube insertion in intubated and unconsciousness patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
 Comparison of the number of success in NG tube placement in the combined method with the conventional method

Timepoint
 Immediately after NG insertion

Method of measurement
 Checking the correct placement by Injecting 20cc of Bolus air into Tube and checking the bulb sound in stomach by stethoscope

2

Description
 Comparing the number of attempts to insert the tube in the combined method with the conventional method

Timepoint
 Immediately after NG insertion

Method of measurement
 Correct NG tube Placement on the first or second attempt is considered a success. Each attempt is equivalent to a duration of less than 90 seconds

3

Description
 Comparison of the elapsed time for tube placement in the combined method with the conventional method

Timepoint
 Immediately after NG insertion

Method of measurement
 Placement time measurement with chronometer

4

Description
 Comparison of immediate complications caused by tube placement in the combined method with the conventional method

Timepoint

Immediately after NG insertion

Method of measurement

Immediate complications include bleeding due to traumatization, twisting of the tube, bradycardia during tube placement, entering the nasogastric tube into the trachea, which is measured after tube placement.

Secondary outcomes

empty

Intervention groups

1

Description

1. In the combined method, first, the tube that is kept at 4 degrees is filled with cold normal saline (4 degrees) with the help of a gavage syringe, and the tube is clamped to prevent the saline from escaping and to prevent the tube from heating up over time the NG tube will be placed in a duration of less than 60 seconds after exiting the refrigerator and the temperature of tube will be measured before placement. 2. The tube enters the nostril at 90 degrees and in the hyperextension position from the side opposite to the entrance of the tracheal tube in the pharynx, so that if the tracheal tube is in the left part of the pharynx, it is entered through the right nostril. 3. After the beginning of the tube reaches the nasopharynx, the patient's head changes to flexion and is turned to the opposite side of the tracheal tube relative to the position of the lips, so that if the tube is fixed in the corner of the left lip, the neck is turned towards turns right. 4. In the mentioned position, nasogastric intubation continues until the marked amount reaches the patient's stomach. The amount of tube placement is calculated by the zen+10 method. 5. The normal saline in the tube is aspirated and the correctness of intubation is controlled. 6. The correctness of intubation is done by injecting 20 cc of air quickly and confirming the sound in the stomach by auscultation of the stomach. In case of failure in the first attempt within 90 seconds, intubation is performed with the failed method. In case of failure after two attempts, intubation failure is recorded and then intubation is done with the help of usual methods or other methods by nurses or doctors.

Category

Treatment - Devices

2

Description

In the control group, nasogastric intubation is performed in unconscious patients and intubation is performed in the conventional way (blind insertion).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department of Imam Reza hospital

Full name of responsible person

Saeed Razghandi

Street address

Doktora Corss road. Imam Reza hospital . Mashad city

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2

Recruitment center

Name of recruitment center

Emergency department of Hasheminezhad hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Vice president of research and technology

Street address

Azadi Square , Mashad city , Khorasan Razavi Province

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Saeed Razghandi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Hesam Sharifipour

Position

Nursing administratorship

Latest degree

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Other areas of specialty/work

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

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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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