

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Placing a Naso Gastric Tube (NGT) with a Rope wire guid in Unconscious patients with an endotracheal tube

Protocol summary

Study aim

Increase the success rate of the Naso Gastric tube insertion

Design

Two arm parallel group randomised trial and outcome assessment in 130 patients

Settings and conduct

This study was carried out at Sina Hospital affiliated to the University of Tehran in anesthetized patients who have an endotracheal tube and are needed to the NG tube.

Participants/Inclusion and exclusion criteria

incusion criteria ,All patients with an endotracheal tube and for any reason need an NG tube Any obstruction in nostril, nasopharynx and coagulopathy was excluded

Intervention groups

All patients have anesthetized and reduced consciousness that have an endotracheal tube and need nNG tube. They are divided into two groups of intervention and control. In intervention group after lubrication the intrance of NG tube a bowden wire inserted into the tube until the end then the nostril was lubricated with jel passing the NG tube through the nose and reching to the hypopharynx some one do the jow trust and we try to pass the NG through the esophagous untill first line on NG rech to the nostril,at this time another person began to withdraw bowden wire and We will continue to insert the tube to the required location In the control group, these steps are carried out without putting Bowden wire

Main outcome variables

The time spent on putting NG Number of attempts to place NG The occurrence of any complications during the delivery of NG

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130304012695N4**

Registration date: **2020-06-23, 1399/04/03**

Registration timing: **retrospective**

Last update: **2020-06-23, 1399/04/03**

Update count: **0**

Registration date

2020-06-23, 1399/04/03

Registrant information

Name

mohammadreza khajavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6312 1220

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khajavim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2019-09-24, 1398/07/02

Actual recruitment start date

2019-02-09, 1397/11/20

Actual recruitment end date

2020-02-09, 1398/11/20

Trial completion date

2020-02-24, 1398/12/05

Scientific title

Placing a Naso Gastric Tube (NGT) with a Rope wire guid in Unconscious patients with an endotracheal tube

Public title

NG tube insetion with guide wire

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All intubated patients that need NG tube
Exclusion criteria:
Any deformity in nostril and obstruction in nasopharynx

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **130**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize patients with inclusion criteria Block balanced randomization is used.Before studying, one of the person who is not a member of the research team performs the randomization process by using Random generator software, forms four blocks for the intervention and control group. The complete cards of the four blocks are given to the head of the operating room, who is unaware of the study, in an envelope. A card is given to the patient after patient entrance to operating room.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of school of medicine tehran university of medical scieences

Street address

sina hospital-hasan abad sq-emam khomeni st.

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Tehran

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Postal code

1136746911

Approval date

2018-10-06, 1397/07/14

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.456

Health conditions studied

1

Description of health condition studied

Gastrointestinal diseases

ICD-10 code

K31.9

ICD-10 code description

Disease of stomach and duodenum, unspecified

Primary outcomes

1

Description

Number of times and time spent on NG placement

Timepoint

At the same time that we carry out the procedure

Method of measurement

The length of time that NG passes through the nose tip to reach the stomach

Secondary outcomes

1

Description

Number of failures

Timepoint

During insertion of NG tube

Method of measurement

If the NG tube does not enter the stomach and we do not hear the sound of air passing through the stomach

2

Description

Complications such as bleeding or insertion of tube to trachea

Timepoint

During insertion of NG tube

Method of measurement

Existence of blood in the throat or nose and hearing breathing sounds from the NG tube

Intervention groups

1

Description

Intervention group: The placement of a NG tube in patients with an endotracheal tube is examined by a special guide called rope wire, which is inserted into the NG tube and the speed of passage from nose, nasopharynx and esophagus Will be evaluated. The speed of NG placement without guide wire Will be evaluated

Category

Treatment - Devices

2**Description**

Control group: The gastric tube is passed through the nose without a guide wire, and after the tube reaches the throat, the mandible is pulled up to facilitate insertion of the tube to esophagus then the time of passage of the tube and placement in the stomach and the success rate of this method in correct placement of the tube in the stomach will be evaluated

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina Hospital

Full name of responsible person

Mohammad Reza khajavi

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Sina Hospital Hassan Abad sq, Emnam Khomini st.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Khajavi

Position

professor of anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

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Full name of responsible person

Mohammad Reza Khajavi

Position

professor

Latest degree

Specialist

Other areas of specialty/work

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the main study data

When the data will become available and for how long

6 month

To whom data/document is available

University and industry researchers

Under which criteria data/document could be used

Share experiences

From where data/document is obtainable

Dr. Khajavi e-mail address

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

Requested by email respons within a week

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

Tehran University of Medical Sciences

Full name of responsible person

Sharareh Jahangiri

Position

Specialist

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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