

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Incidence of respiratory and ventilator-associated events in patients intubated with RAE or spiral endotracheal tubes in head and neck surgery

Protocol summary

Study aim

Incidence of respiratory and ventilator-associated events in patients intubated with RAE or spiral endotracheal tubes in head and neck surgery

Design

500 patients based on the studies and statistical calculations that meet the inclusion criteria and according to the order of referral will be selected and base on Randlist software will be divided into control and intervention groups. In the control group, the RAE tube will be used for endotracheal intubation and in the intervention group, the spiral tube will be used. This study is a randomized, double blind clinical trial with control group

Settings and conduct

study will be performed in the operating room of Imam Reza Hospital in Tabriz. After premedication with fentanyl 1 µg/kg, midazolam 0.02 mg/kg, induction of anesthesia will be done by propofol 3 mg/kg and atracurium 40-50 mg. Then, hemodynamic variables including blood pressure, heart rate and oxygen saturation will be measured and recorded every 5 minutes by the anesthesiologist. Penlon/Prima SP2 Ventilator will be used in all patients. Respiratory modes will be in volume control modes with a target volume of 8-6 cc/kg and the upper limit of acceptable airway pressure will be adjusted to 40 cmH₂O. increase airway pressure, tube kinking, inability to properly ventilate and require tube inspection or endotracheal tube replacement will be recorded. In this study, anesthesiologists and patients will be blinded to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient undergoing head and neck surgery with ASA 1 & 2. Exclusion criteria: obstructive sleep apnea Respiratory tract infection over the last 2 weeks wheeze 3 or more times in 12 months wheezing during exercise

Intervention groups

RAE endotracheal tube will use in control group and

spiral endotracheal tube will use in intervention group

Main outcome variables

ventilatory and respiratory complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150125020795N9**

Registration date: **2019-12-11, 1398/09/20**

Registration timing: **prospective**

Last update: **2019-12-11, 1398/09/20**

Update count: **0**

Registration date

2019-12-11, 1398/09/20

Registrant information

Name

Samad Golzari

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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golzaris@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Incidence of respiratory and ventilator-associated events in patients intubated with RAE or spiral endotracheal tubes in head and neck surgery

Public title

respiratory and ventilator-associated events in patients intubated with RAE or spiral endotracheal tubes

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing head and neck surgery are classified as Class 1 or 2 as defined by the ASA Class

Exclusion criteria:

Patients with a history of obstructive sleep apnea
Respiratory tract infection over the last 2 weeks Wheeze 3 or more times in 12 months A history of asthma in the absence of wheezing Wheezing during exercise
Persistent nocturnal dry cough

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **500**

Randomization (investigator's opinion)

Randomized

Randomization description

according to the order of referral will be selected and base on Randlist software will be divided into controlo&intervention groups

Blinding (investigator's opinion)

Double blinded

Blinding description

An anesthesiologist who assesses the ventilatory and respiratory complications of patients will be blind. Patients will also be unaware of the type of endotracheal tube used in intubation

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz university of medical sciences, Golgasht st, Tabriz

City

Tabriz

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East Azarbaijan

Postal code

5166614766

Approval date

2019-07-03, 1398/04/12

Ethics committee reference number

IR.TBZMED.REC.1398.404

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

Intubation with RAE and spiral endotracheal tube in head and neck surgery

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

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

Amount of airway pressure despite anesthesia and muscle relaxation

Timepoint

The entire duration of surgery

Method of measurement

Ventilation and respiratory complications questionnaire

2**Description**

Endotracheal Tube kinking

Timepoint

The entire duration of surgery

Method of measurement

Ventilation and respiratory complications questionnaire

3**Description**

Amount of proper ventilation

Timepoint

The entire duration of surgery

Method of measurement

Ventilation and respiratory complications questionnaire

4

Description

Need to endotracheal tube inspection

Timepoint

The entire duration of surgery

Method of measurement

Ventilation and respiratory complications questionnaire

5

Description

Need to endotracheal tube replacment

Timepoint

The entire duration of surgery

Method of measurement

Ventilation and respiratory complications questionnaire

Secondary outcomes

1

Description

patient saturation

Timepoint

The entire duration of surgery

Method of measurement

Based on continuous pulse oximeter monitoring

Intervention groups

1

Description

Intervention group: Patients undergoing spiral tube intubation

Category

Treatment - Devices

2

Description

Control group: Patients undergoing RAE tube intubation

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamreza hospital

Full name of responsible person

Samad jamal eslam golzari

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Emamreza hospital,Golgasht street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Samad Jamal Eslam Golzari

Position

Consultant

Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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

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

All of the study participants' individual data is shared after unidentifiable individuals.

When the data will become available and for how long

access period will be 6 months after printing results

To whom data/document is available

Documents will be available for people working in academia institution and also people working in businesses.

Under which criteria data/document could be used

There are no specific restrictions on the use of data or documentation

From where data/document is obtainable

You can contact Dr. Samad Jamal Islam Golzari for the required documentation or data through the following contact ways: adress: Anesthesiology department, faculty of medicine, Golgasht street Tel number: 0984133341994 mobile number: 0989141151894 Email adress: golzaris@tbzmed.ac.ir

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

Correspondence through email only

Comments