

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Effect of the education program on nurses' knowledge and performance in the endotracheal tube cuff management

#### Protocol summary

##### Summary

This study is a randomized and single blind study which aims to examine the effect of educational program on nurses' knowledge and practice in management of tracheal tube cuff in intensive care unit patients. Subjects will be selected from four hospitals in Tehran, Iran including Imam Khomeini, Sina, Dr, Shariati and Rasool Akram. Subjects are intubated patients and nurses form intensive care units. Inclusion criterion for nurses is work experience in intensive care units at least for one-year. In addition, inclusion criteria for patients are age over 18-year old; having endotracheal tube for more than 48 hours; having no injuries or damage in face and neck; having no tumors in the respiratory tract and stable hemodynamic conditions. The intervention is an educational program about endotracheal cuff management. The content will provide to subjects in lecture and written material. Nurses' knowledge and practice will be measured two weeks before and after education through self-designed questionnaire and check list. It is expected that educational program will increase awareness and improve performance and reduce complications of endotracheal tube cuff may lead nurses.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013112615560N1**  
Registration date: **2013-12-25, 1392/10/04**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-12-25, 1392/10/04

##### Registrant information

##### Name

rogheah javadi Ali Gheshlaghi

##### Name of organization / entity

TUMS

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

javadi\_r@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Nursing Faculty of Tehran University of Medical Sciences

##### Expected recruitment start date

2013-12-07, 1392/09/16

##### Expected recruitment end date

2014-01-06, 1392/10/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of the education program on nurses' knowledge and performance in the endotracheal tube cuff management

##### Public title

Effect of education in endotracheal tube cuff management

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criterion for nurses: working experience in intensive care units at least for one-year. Inclusion criteria for patients are age over 18-year old; having endotracheal tube for more than 48 hours; having no

injuries or damage in face and neck; having no tumors in the respiratory tract and stable hemodynamic conditions. Exclusion criterias for nurses are leave a job or retirement along sampling (before and after intervention), and for patients are death or weaning from endotracheal tube.

**Age**

From **18 years** old to **100 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Tehran University of Medical Sciences

**Street address**

tehran medisine university- poor sina Ave- keshavarz  
Bolvd- tehran-Iran

**City**

tehran

**Postal code****Approval date**

2013-08-07, 1392/05/16

**Ethics committee reference number**

827

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

Tracheal tube cuff

**ICD-10 code**

Y70

**ICD-10 code description**

Anaesthesiology devices associated with adverse incidents

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

Awareness

**Timepoint**

2 weeks before and after intervention

**Method of measurement**

Self-designed awareness questionner

**2****Description**

Performance

**Timepoint**

2 weeks before and after intervention

**Method of measurement**

Self reporting/ self-designed performance check list

**Secondary outcomes****1****Description**

Tracheal tube cuff management

**Timepoint**

2 weeks before and after intervention

**Method of measurement**

Check list

**Intervention groups****1****Description**

Education of Intervention groups; at beginning mass education and then person to person training at the patient's bedside by lecture, questions and answers method with usage of pamphlet for 3 days.

**Category**

Other

**2****Description**

in control groups no intervention

**Category**

Other

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

Sina Hospital

**Full name of responsible person****Street address****City**

Tehran

## 2

### Recruitment center

**Name of recruitment center**

Shariati Hospital

**Full name of responsible person****Street address****City**

Tehran

## 3

### Recruitment center

**Name of recruitment center**

Rasool Akram Hospital

**Full name of responsible person****Street address****City**

Tehran

## 4

### Recruitment center

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person****Street address****City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Masud Yunesian

**Street address**

Research Deputy department- 16 Azar ave- keshavarz  
bolvard- tehran

**City**

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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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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## Person responsible for scientific inquiries

### Contact

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Mohammadi Noraldin

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## Person responsible for updating data

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*