

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparing the effect of head of bed elevation 30 and 45 degree on incidence of ventilator associated pneumonia in patients admitted to Intensive Care Units.

#### Protocol summary

##### Summary

1). Main aim of current study is investigating effects of head of bed elevation 30, 45 degree on incidence of ventilator associated pneumonia among admitted patients in ICU. 2) Design study as randomized clinical trial with control group. 3) Method: 120 patients with max 8 hours intubation in ICU as randomized within two groups as control and intervention groups. 4) All participants should intubated now or at least they should intubated up to 8 hours before and they should not have pneumonia or pressure ulcers. 5). Interference: intervention group should be under 30 or 45 degree within 3 days and they should receive all routine cares. Control group were not under any angles and only receive all routine cares . 6). The primary outcome variable is ventilator associated pneumonia and secondary outcome variable is pressure ulcers.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120225345N1**  
Registration date: **2016-04-29, 1395/02/10**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-04-29, 1395/02/10

##### Registrant information

##### Name

Leila Kalhor

##### Name of organization / entity

Iran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4686 6474

##### Email address

kalhor.l@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research, Iran University of Medical Science

##### Expected recruitment start date

2016-04-13, 1395/01/25

##### Expected recruitment end date

2016-10-17, 1395/07/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of head of bed elevation 30 and 45 degree on incidence of ventilator associated pneumonia in patients admitted to Intensive Care Units.

##### Public title

Comparing the effect of head of bed elevation 30 and 45 degree on incidence of Ventilator Associated Pneumonia in patients admitted to Intensive Care Unites. unites.

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria's: Age more than 18 years old, Lack of ventilator associated Pneumonia, Hospitalized patients in ICU with mechanical ventilation up to max 8 hours after admission and intubation of patients, Lack of pressure ulcers, Lack of spine injuries and or unstable pelvic

fractures. Exclusion criteria's : Patient death, Patients who were in semi recumbent position less than 6 hours within 24 hours, Patients who have pressure ulcers on 45 degree, Separating patients from mechanical ventilation or transport to other units before 72 hours.

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double 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 Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, Shahid Hemmat highway, Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2015-11-29, 1394/09/08

#### Ethics committee reference number

IR.IUMS.REC.1394.9311449007

## Health conditions studied

### 1

#### Description of health condition studied

Pneumonia

#### ICD-10 code

J18

#### ICD-10 code description

Pneumonia, organism unspecified

## Primary outcomes

### 1

#### Description

Ventilator Associated Pneumonia

#### Timepoint

3 days after intervention

#### Method of measurement

CPIS scale

## Secondary outcomes

### 1

#### Description

pressure ulcer

#### Timepoint

3 days after intervention

#### Method of measurement

Braden Scale

## Intervention groups

### 1

#### Description

In intervention group, patients positioned 30,45 degree for 3 days. Head of bed elevation measure with goniometer.

#### Category

Prevention

### 2

#### Description

In control group, patients not position in degree and only received routine care.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

General ICU, Khatamol Anbia Hospital

##### Full name of responsible person

Leila Kalhor

##### Street address

Khatamol Anbia hospital, Shahid Rashid Yasemi st, Valiasr st, Above Vanak sq, Tehran.

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Medical ICU, Rasool Akram Hospital

##### Full name of responsible person

Leila Kalhor

**Street address**

Rasol Akram hospital, Niayesh st, Sattarkhan st, Tehran

**City**

Tehran

**3**

**Recruitment center**

**Name of recruitment center**

Medical ICU, Steroc ICU

**Full name of responsible person**

Leila Kalhor

**Street address**

Firoozgar hospital, Beh Afarin st, Karim khane Zand st, Valiasr st, Tehran

**City**

Tehran

**4**

**Recruitment center**

**Name of recruitment center**

Medical ICU, Haftom Tir Shohada Hospital

**Full name of responsible person**

Leila Kalhor

**Street address**

Haftom Tir hospital, Rajae st, Rey City, Tehran

**City**

Tehran

**5**

**Recruitment center**

**Name of recruitment center**

Medical ICU, Emam Sajad Hospital

**Full name of responsible person**

Leila Kalhor

**Street address**

Emam Sagad hospital, Valiasr st, Shahriar

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor Of Research, Iran University of Medical Science

**Full name of responsible person**

Seyyed Ali Javade Moosavi

**Street address**

Iran University of Medical Science, Shahid Hemmat highway, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor Of Research, Iran University of Medical Science

**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**

School of Nursing & Midwifery of Iran University of Medical Science

**Full name of responsible person**

Leila Kalhor

**Position**

Post Graduate Student in Nursing

**Other areas of specialty/work**

**Street address**

School of Nursing & Midwifery, Shahid Rashid Yasemi St, After Vanak Square, Vali Asr St, Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 21 8888 2886

**Fax**

**Email**

Leila.kalhor22@gmail.com; kalhor.l@tak.iums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

School of nursing & midwifery of Iran University of Medical Science

**Full name of responsible person**

Tahereh Najafi Ghezeljeh

**Position**

Ph.D in Nursing

**Other areas of specialty/work**

**Street address**

School of Nursing & Midwifery, Shahid Rashid Yasemi St, After Vanak Square, Vali Asr St, Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 21 8888 2885

**Fax**

**Email**

Najafi.t@iums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

School of Nursing & Midwifery of Iran University of  
Medical Science

**Full name of responsible person**

Leila Kalhor

**Position**

Post Graduate Student in Nursing

**Other areas of specialty/work**

**Street address**

School of Nursing & Midwifery, Shahid Rashid Yasemi  
St, After Vanak Square, Vali Asr St, Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 21 8888 2885

**Fax**

**Email**

Leila.kalhor22@gmail.com; kalhor.l@tak.iums.ac.ir

**Web page address**

## 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*