

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