

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Compared rotated endotracheal tube fixation with routine method on its Complications in intubated patient in Intensive Care Unit

Protocol summary

Summary

This randomized, single-blinded controlled study to compare the effect of duration And rotational stabilization of the endotracheal tube on incidence of complications in patients intubated intensive care unit is done. Patients 20 to 65 years with a GCS of less than 8 who were intubated in the past 48 hours, samples are selected. The sample size was 132 patients. . After obtaining the written consent of the legal guardian, patients were randomly assigned to two experimental and control groups are divided. Group Routine, endotracheal tube fixation rotation every 24 hours (n =66) is performed. The experimental group underwent endotracheal tube fixation rotation every 12 hours (n = 66) are. Endotracheal tube for rotational positions in three different directions (right corner of the mouth, the mouth, and left corners of the mouth) which can be moved in three days. Other conditions such as type of bond fixator care of endotracheal tube intubation, length and width and frequency of endotracheal tube cuff deflation will be the same. In both groups to determine the effects of intervention External jugular venous pressure, displacement of the endotracheal tube,, oral hygiene, skin integrity and extubation will be investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041927489N1**
Registration date: **2016-05-09, 1395/02/20**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-09, 1395/02/20

Registrant information

Name

Fateme Rafiei

Name of organization / entity

Hamedan ,University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0583

Email address

m.rafee@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compared rotated endotracheal tube fixation with routine method on its Complications in intubated patient in Intensive Care Unit

Public title

the effect of rotated endotracheal tube fixation on its Complications

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: - patients with an endotracheal tube through the mouth, Age between 20 and 65, Patients who are intubated for at least the past 48 hours, Lack of skin

disease (eczema, psoriasis, skin cancer, etc.),Lack of diseases of the mouth before being intubated,Normal jugular venous pressure (6 to 8 cm) water,Patients have PEEP \leq 10 cm² H₂O,Lack of metabolic diseases (diabetes),Lack of valvular heart disease - the GCS under 8,Exclusion criteria: Extubated,Death before the end of study Elevated jugular venous pressure due to other cases such as cardiac tamponade, hypervolemia, and ...

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

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

Hamedan University of Medical Sciences

Street address

Hamedan - street shahyd fahmide - across from People,'s Park

City

Hamedan

Postal code

38698-65178

Approval date

2016-04-11, 1395/01/23

Ethics committee reference number

IR.UMSHA.REC.1395.4

Health conditions studied

1

Description of health condition studied

Complications of medical and surgical care (Y40-Y84)

ICD-10 code

Y84.8

ICD-10 code description

Other medical procedures

Primary outcomes

1

Description

External jugular venous pressure

Timepoint

During the three days before and 15 minutes after changing positions

Method of measurement

Ruler (cm)

2

Description

Displacement of the Endotracheal Tube

Timepoint

During the three days before and 15 minutes after changing positions.

Method of measurement

Ruler (cm)

3

Description

Oral hygiene

Timepoint

Every 24 hours during three days

Method of measurement

Scale BRUSHED

4

Description

Extubation

Timepoint

After repositioning the endotracheal tube in three days

Method of measurement

Observation

5

Description

Skin integrity

Timepoint

Every 24 hours during three days

Method of measurement

Scale Kupas et al

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:: fixed rotational endotracheal tube every 12 hours (n = 66)

Category

Other

2**Description**

control group : fixing an endotracheal tube rotation every 24 hours (n = 66)

Category

Other

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

Hamedan Besat hospital

Full name of responsible person

Fateme Rafiei

Street address

Hamedan

City

Hamedan ,SHahied Beheshty Blvd ,Hamedan Besat hospital

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian- Deputy Minister for Research and Technology

Street address

Hamedan, SHaheid Beheshty Blvd-across from People's Park

City

Hamedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mahnaz KHatiban

Position

Nursing PhD

Other areas of specialty/work**Street address**

Hamedan,SHaheid Beheshty Blvd , across from People's Park

City

Hamedan

Postal code**Phone**

+81 38380583

Fax**Email**

mahnaz.khatiban@gmail.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mahnaz KHatiban

Position

Nursing PhD

Other areas of specialty/work**Street address**

Hamedan , SHaheid Beheshty Blvd,across from People's Park

City

Hamedan

Postal code**Phone**

+81 38380583

Fax**Email**

mahnaz.khatiban@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan,University of Medical Sciences

Full name of responsible person

Fateme Rafiei

Position

Master of Science in Nursing/ nurse

Other areas of specialty/work**Street address**

Hamedan, SHahied Beheshty Blvd,across from the People's Park

City

Hamedan

Postal code

38698-65178

Phone

+81 38380583

Fax

+98 81 3838 0447

Email

m.rafee@edu.umsha.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*