

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of a designed care plan on incidence of aspiration and ventilator associated pneumonia in intubated patients hospitalized in the ICU in Ali Ebne Abitaleb Hospital, Zahedan 2016

Protocol summary

Summary

1) Objectives: This study aimed to determine the effect of designed care plan on the incidence of aspiration and ventilator associated pneumonia in patients admitted to the ICU intubated Aliebn Abitalib Hospital in zahedan 2016. 2) Design: this is a randomized Single blind study. 3) Setting and conduct: The available sampling will be used, then patients are divided to the control or study group by random allocation. 4) Participants including major eligibility criteria: The study population included patients admitted to the ICU intubated and receiving mechanical ventilation by nasogastric tube fed and is eligible for the study. The available sampling will be used based on including criteria's from intubated patients.5) Intervention: The control group receives routine care in the prevention of VAP and incidence of aspiration. In the intervention group, patient care in a care plan designed (which will be described below) is carried out. In patients in both groups before the intervention, MCPIS will be used and patients with VAP will be excluded. In the intervention group, designed care plan to reduce the incidence of aspiration which is composed of four parts, in the intervention days (three days from the second day after intubation) will be done. The care plan has the following steps: raising the head of the bed to 30 degrees or more, the determination and management of gastric residual volume, abdominal massage, and oral care. 6) Main outcome measures (variables): Ventilator associated pneumonia, Aspirations, gastric residual volume.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072729100N1**
Registration date: **2016-10-15, 1395/07/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-15, 1395/07/24

Registrant information

Name

Parastoo Mohamadi

Name of organization / entity

Zahedan University of Medicine

Country

Iran (Islamic Republic of)

Phone

+98 54 3343 0059

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mohammadi.p93@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a designed care plan on incidence of aspiration and ventilator associated pneumonia in intubated patients hospitalized in the ICU in Ali Ebne

Public title

The effect of a designed care plan on incidence of aspiration and ventilator associated pneumonia in intubated patients

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria of the study were: being 16–65 years of age; the second day of intubation; the MCPIS score more than 5 or equal; the patient doesn't have pneumonia, ARDA, COPD; using only standard formulas for feeding; monitoring with mechanical ventilation for at least 96 h. The patients with tracheostomy; abdominal wound; surgery; pregnancy and radiotherapy; ileus; diarrhea; and those using prokinetic agents; remove the NGT; changing the endotracheal tube were excluded from the study.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Ethics committee of Zahedan University of Medicine

Street address

Khalidj fars blv, Hesabi square, Zahedan

City

Zahedan

Postal code

98167-43463

Approval date

2016-07-10, 1395/04/20

Ethics committee reference number

IR.ZAUMS.REC.1395.124

Health conditions studied

1

Description of health condition studied

Aspiration pneumonia

ICD-10 code

J69

ICD-10 code description

Aspiration pneumonia (due to): NOS food (regurgitated) gastric secretions milk vomit

Primary outcomes

1

Description

Ventilator associated pneumonia

Timepoint

Before intervention and at the end of intervention

Method of measurement

In this study, pneumonia means the MCPIS score more than 5. The highest score is 10. If patients earn more than 5 point, the diagnosis of VAP is pretended.

2

Description

Aspirations

Timepoint

At the intervention days, before morning and evening massage

Method of measurement

In this study, the means of aspiration is the number of oral discharge PH that measures by test tapes. It measures each day before massage. The score less than 6 represents the aspiration.

3

Description

gastric residual volume

Timepoint

in intervention days, at morning and evening, before gavage

Method of measurement

it means the volume of gastric content that measure by syringe before each gavage.

Secondary outcomes

1

Description

age

Timepoint

before intervention

Method of measurement

based on patient documented data.

2

Description

sex

Timepoint

before intervention

Method of measurement

according to phenotype

3

Description

history of ICU admission

Timepoint

before intervention

Method of measurement

Patient recent hospitalization in ICU Prior to his current hospitalization

4

Description

Underlying disease

Timepoint

before intervention

Method of measurement

medical disease such as heart, renal, neurologic, gastric, and Pulmonary except for COPD, ARDS, and pneumonia

5

Description

volume of nutritional solution

Timepoint

before gavage within interventional days

Method of measurement

The nutritional solution volume that is prescribed by doctors

6

Description

times of endotracheal suctioning

Timepoint

in each shift within interventional days

Method of measurement

The number of times that endotracheal suctioning can be performed by a nurse per shift

7

Description

The patient's level of consciousness

Timepoint

During the intervention days, each hour

Method of measurement

GCS score of the patient in accordance with standard scale of Glasgow is controlled by a nurse every hour.

8

Description

Level of sedation

Timepoint

in each shift within interventional days

Method of measurement

RASS is a scale score that is measured by the nurse in each shift

9

Description

The size of the endotracheal tube

Timepoint

before intervention

Method of measurement

Internal diameter of endotracheal tube

10

Description

Endotracheal tube cuff pressure

Timepoint

in each shift within interventional days

Method of measurement

Endotracheal tube cuff pressure measured by the nurse on each shift by a manometer for measurement.

Intervention groups

1

Description

In the intervention group, designed care plan to reduce the incidence of aspiration which is composed of four parts, in the intervention days (three days from the second day after intubation) will be done. The care plan has the following steps: raising the head of the bed to 30 degrees or more, the determination and management of gastric residual volume, abdominal massage, and oral care.

Category

Other

2

Description

The control group receives routine care in the prevention of VAP and incidence of aspiration.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Parastoo Mohamadi

Street address

School of Nursing and Midwifery, Mashahir Sq, Zahedan,

City

zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences, Vice
chancellor for research

Full name of responsible person

Hoshang Rafighdost

Street address

University of Medical Sciences, Docter Hesabi sq,
Zahedan Zahedan

City

Zahedan

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

Yes

Title of funding source

Zahedan University of Medical Sciences, Vice chancellor
for research

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**

Nursing and Midwifery Faculty

Full name of responsible person

Parastoo Mohamadi

Position

Msn student in Critical Care Nursing

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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