Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 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

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Name of organization / entity

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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

Abitaleb Hospital, Zahedan 2016

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 dosnt 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 endothracheal 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 Medicin
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 syring 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 addmition
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 ecsept 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
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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