

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of body position on gastric residual volume in patients undergoing mechanical ventilation in intensive care units.

Protocol summary

Summary

This study is a double group crossover clinical trial without blinding which is setup on 36 patients hospitalized in intensive care units of Besat hospital in Tehran, Iran. The purpose of this study is assessment the effect of body position on gastric residual volume in patients undergoing mechanical ventilation in intensive care units. Patients, who have the inclusion criteria of research are assigned to group A and group B pseudo randomly. On the first day of study, group A patients, are placed in the semi recumbent position after the first gavage, and in right lateral position after the second gavage with a washout period of 3 hours. Then, patients of group B, are placed in right lateral position after the first gavage and in semi recumbent position after the second gavage after 3 hours. Before each feeding, at first researcher measures the patient's gastric residual volume with standard gavage syringe and registers them. Finally, gastric residual volumes are compared in 2 groups in every mentioned position. All Patients feeding will be according to continuous bolus method. Meanwhile, patients apache3 score will be calculated and compared in 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110623446N6**
Registration date: **2016-05-13, 1395/02/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-13, 1395/02/24

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

This research has been funded by vice chancellor grant for research of AJA University of Medical Sciences

Expected recruitment start date

2016-03-15, 1394/12/25

Expected recruitment end date

2016-06-14, 1395/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of body position on gastric residual volume in patients undergoing mechanical ventilation in intensive care units.

Public title

The effect of body position on gastric residual volume

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients, who are hospitalized in medical intensive care units; Age between 18-65 years; Feeding via naso-gastric tube; Patients, who are undergoing invasive mechanical ventilation 48 hours

before intervention; Taking no drugs that affect the gastric motility during recent week before intervention; Patients, who do not have acute gastric disorders; Patients, who are not pregnant; Patients, who do not have any limitation or contraindications of body change position. Exclusion criteria: Taking drugs that affect gastric motility during the study; Increase the level of conscious and the ability of eating during the study; Change of feeding route; Discharging or transferring of patient from intensive care unit during the study; Weaning of the patient from mechanical ventilation machine.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features

Allocate the groups into A and B will be according to pseudo randomization method.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of AJA University of Medical Sciences

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Approval date

2016-02-15, 1394/11/26

Ethics committee reference number

IR.AJAUMS.REC.1394.48

Health conditions studied**1****Description of health condition studied**

relation between body position and gastric residual volume in patients undergoing mechanical ventilation in intensive care units

ICD-10 code

w78

ICD-10 code description

gastric content

Primary outcomes**1****Description**

Gastric residual volume

Timepoint

Before and 3 hours after intervention

Method of measurement

With standard gavage syringe

Secondary outcomes

empty

Intervention groups**1****Description**

In this study, researcher placed the patients in group A in semi recumbent position after the first gavage, and in right lateral position after next gavage for 3 hours. Meanwhile, before each feeding, first she measures the patient gastric residual volume with standard gavage syringe and registers them.

Category

Other

2**Description**

In this study, researcher placed the patients in group B in right lateral position after the first gavage and in semi recumbent position after next gavage for 3 hours. Meanwhile, before each feeding, first she measures the patients gastric residual volume with standard gavage syringe and registers them.

Category

Other

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

Besat hospital of Tehran

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, AJA University of Medical Sciences

Full name of responsible person

Dr. Kamran Azma

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, AJA 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

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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