

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The Relationship Between changing patient position in Bed with Intra Abdominal Pressure and its Consequences among mechanically ventilated patients admitted to intensive care units

Protocol summary

Study aim

Determine the relationship between changing patient position in Bed with Intra Abdominal Pressure and its Consequences among mechanically ventilated patients admitted to intensive care units

Design

Before and After clinical trial

Settings and conduct

This study will be done among mechanically ventilated patients admitted to intensive care units in Imam Khomeini teaching hospital in Urmia. Intra Abdominal pressure will be measured by Intra Vesical Pressure measurement by central venous pressure measurement manometer.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age > 18 years old Mechanically ventilated patient Have indwelling urine catheter in place Score of Critical care Pain Observation Tool ≤ 2 Length of ICU stays ≥ 48 hours; Exclusion Criteria: Unable to change position Nonurgenic bladder Bladder rupture Hematuria Heart failure and Pulmonary edema Pregnancy Excessive obesity Acute abdominal patients Probability of survival less than 24 hours

Intervention groups

We will measure the Intra Abdominal Pressure in each of the different situations (15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) first time before changing the position of the patient in 0 degree head of bed, second time, 20 minute after changing position, and third time, 20 minutes after returning to 0 degree. Interval among the interventions (put the patients in different positions of 15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) will be 2 hours. Then each patient will be compared with him/herself in each different situation.

Main outcome variables

Intra Abdominal Pressure; Mean Arterial Pressure; Abdominal Perfusion Pressure; Mean Airway Pressure; Peak Inspiratory Pressure; Plateau Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181105041560N1**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-19, 1397/11/30**

Update count: **0**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

Yusef Haghighi moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4961

Email address

hagigym@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-17, 1397/11/28

Expected recruitment end date

2019-04-17, 1398/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Relationship Between changing patient position in Bed with Intra Abdominal Pressure and its Consequences among mechanically ventilated patients admitted to intensive care units

Public title

The Relationship Between changing patient position in Bed with Intra Abdominal Pressure and its Consequences among mechanically ventilated patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age > 18 years old Mechanically ventilated patient Have indwelling urine catheter in place Scor of Critical care Pain Observation Tool ≤ 2 Length of ICU stays ≥ 48 hours

Exclusion criteria:

Unable to change position Norogenic bladder Bladder rupture Hematuria Heart failure and Pulmonary edema Pregnancy Excessive obesity Acute abdominal patients Probability of survival less than 24 hours

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Urmia University of Medical Sciences

Street address

Next to the Emergency department., Jahad Ave., Resalat Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-12-29, 1397/10/08

Ethics committee reference number

IR.UMSU.REC.1397.358

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

Intra Abdominal Presure

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Intra Abdominal Pressure:The intra-abdominal pressure is a sustained pressure that lies inside the abdominal cavity.

Timepoint

we will Measure inetra abdominal pressure in each of the different situations(15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) first time before changing the position of the patient in 0 degree head of bed, second time, 20 minute after changing position,and third tim, 20 minut after returning to 0 degree.interval among the interventions(put the patients in different positions of 15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) will be 2 hours.

Method of measurement

Measuring Intera-vesical pressure by water manometer of central vein pressure measuring device.

Secondary outcomes**1****Description**

Mean Arterial Pressure: It is the average amount of the systemic pressure with normal range of 70 to 105 mm Hg.

Timepoint

we will Measure the Mean Arterial Pressure in each of the different situations(15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) first time before changing the position of the patient in 0 degree head of bed, second time, 20 minute after changing position,and third tim, 20 minut

after returning to 0 degree.interval among the interventions(put the patients in different positions of 15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) will be 2 hours.

Method of measurement

It will be measured by a monitor device attached to the patient

2

Description

Abdominal Perfusion Pressure:If the intra-abdominal pressure is lowered from the median arterial pressure, abdominal perfusion pressure will be obtained. In adults, it should be above 50 mm Hg to provide adequate ventricular perfusion.

Timepoint

we will measure Abdominal Perfusion Pressure in each of the different situations(15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) first time before changing the position of the patient in 0 degree head of bed, second time, 20 minute after changing position,and third tim, 20 minut after returning to 0 degree.interval among the interventions(put the patients in different positions of 15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) will be 2 hours.

Method of measurement

we will Calculate the Abdominal Perfusion Pressure with subtraction the mean arterial pressure measured by the monitor attached to the patient and intera abdominal pressure measured by water manometer.

3

Description

Mean Airway Pressure:It is the pressure measured at the airway opening, averaged over the entire ventilatory cycle.

Timepoint

we will measure the Mean Airway Pressure in each of the different situations(15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) first time before changing the position of the patient in 0 degree head of bed, second time, 20 minute after changing position,and third tim, 20 minut after returning to 0 degree.interval among the interventions(put the patients in different positions of 15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) will be 2 hours.

Method of measurement

It will be measured by the ventilator device attached to the patient.

4

Description

Peak Inspiratory Pressure:It is the highest level of pressure applied to the lungs during inhalation.

Timepoint

we will measure the Peak Inspiratory Pressure in each of the different situations(15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) first time before changing the position of the patient in 0 degree head of bed, second time, 20 minute after changing position,and third tim, 20 minut after returning to 0 degree.interval among the interventions(put the patients in different positions of 15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) will be 2 hours.

Method of measurement

It will be measured by the ventilator device attached to the patient.

5

Description

Plateau Pressure:It is the pressure of the air ways at the end of inspiration.

Timepoint

we will measure the Plateau Pressure in each of the different situations(15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) first time before changing the position of the patient in 0 degree head of bed, second time, 20 minute after changing position,and third tim, 20 minut after returning to 0 degree.interval among the interventions(put the patients in different positions of 15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) will be 2 hours.

Method of measurement

It will be measured by the ventilator device attached to the patient.

6

Description

Auto PEEP: The Positive End Expratory Pressure in the air ways that is because of inadequate expratory tim.

Timepoint

we will measure the Auto PEEP in each of the different situations(15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) first time before changing the position of the patient in 0 degree head of bed, second time, 20 minute after changing position,and third tim, 20 minut after returning to 0 degree.interval among the interventions(put the patients in different positions of 15 degree, 30 degree, 45 degree, right lateral position with 30 degree, left lateral position with 30 degree) will be 2 hours.

Method of measurement

It will be measured by the ventilator device attached to the patient.

Intervention groups

1

Description

Control group: This study is an interventional study of

the type before and after. In such a way that each person in different states of the body will be used as a witness for himself.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia, Imam Khomeini teaching hospital

Full name of responsible person

Ali Akbar Nasiri

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Ershad Ave., Aiat Allah Modarres Blvd., Imam Khomeini teaching hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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Web page address

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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

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Yusef Haghighi moghadam

Position

PhD in Nursing, Assistant professor Faculty of Nursing & Midwifery School, urmia University of Medic

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Yusef Haghighi moghadam

Position

PhD in Nursing, Assistant professor Faculty of Nursing & Midwifery School, urmia University of Medic

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Person responsible for updating data

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& Midwifery School, urmia University of Medic
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available