

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of endotracheal suctioning with and without normal saline on hemodynamic and respiratory parameters in patients with mechanical ventilation in intensive care unit , rasht,guilan

Protocol summary

Summary

Endotracheal suctioning is common nursing care in intubated patients . nurses commonly instillation normal saline before suctioning procedure . the purpose of instillation N/S is diluting and loosening thick secretions and facilitating mobilisation and remove secretions.however , its efficacy is unsupported by research based evidence .this study is a randomized , , cross-over , clinical trial , done on 74 intubated patients that receive mechanical ventilation,and their hemodynamic status is stable.we lay aside patients had chronic disease and those using cardiac and respiratory medications; using muscle relaxation medications or change setting ventilator within our study and patients that do not require suctioning after 2 hrs. the purpose of this research is to be determined to be affected with each of the method on patients. in the first cycle of study , patients randomly assigned two group. group A (suctioning without N/S) group B (suctioning with instillation 5 cc N/S) , then respiratory and hemodynamic parameters measured once before suctioning and another after suctioning .the next cycle ., rested for 2 hrs, and using cross-over design. two group of patients is interchange.again the whole procedure repeat .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205181174N7**

Registration date: **2012-07-21, 1391/04/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-21, 1391/04/31

Registrant information

Name

Atefeh Ghanbari

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Guilan University Of Medical Science

Expected recruitment start date

2012-07-05, 1391/04/15

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of endotracheal suctioning with and without normal saline on hemodynamic and respiratory parameters in patients with mechanical ventilation in intensive care unit , rasht,guilan

Public title

The effect of normal saline in endotracheal suctioning on hemodynamic and respiratory parameters.

Purpose

Supportive

Inclusion/Exclusion criteria

Patients with the following conditions were included: intubated patients; the ET size is 7-8 fr and to receive volume mechanical ventilation for > 72 hrs and less than for one week; their hemodynamic status is stable (BP > 90 mmHg, urine output of less than 30 ml/h and having balance electrolytes and no dysrhythmia. Exclusion criteria: patients had chronic disease such as: cardiac disease, hypertension, COPD and those using cardiac and respiratory medications; using muscle relaxation medications or change setting ventilator within our study and patients that do not require suctioning after 2 hrs.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

1

Registry name

No

Secondary trial Id

No

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University Of Medical Science

Street address

Guilan University Of Medical Sciences

City

Rasht

Postal code

Approval date

2012-04-17, 1391/01/29

Ethics committee reference number

2910051519

Health conditions studied

1

Description of health condition studied

Patients with impaired respiratory function in ICU

ICD-10 code

J95-99

ICD-10 code description

Other diseases of the respiratory system

Primary outcomes

1

Description

Respiratory parameters include: ETco2

Timepoint

the variable before suctioning and immediately, 15, 30, 45, 30 second and then 1,2,3,4,5 minute after suctioning

Method of measurement

Capnograph

2

Description

respiratory rate

Timepoint

the variable before suctioning and 2 and 5 minute after suctioning

Method of measurement

monitor of ventilator

3

Description

mean airway pressure

Timepoint

the variable before suctioning and 2 and 5 minute after suctioning

Method of measurement

monitor of ventilator

4

Description

peak inspiratory pressure

Timepoint

the variable before suctioning and 2 and 5 minute after suctioning

Method of measurement

monitor of ventilator

5

Description

o2 sat

Timepoint

the variable before suctioning and immediately, 15, 30, 45, 30 second and then 1,2,3,4,5 minute after suctioning

Method of measurement

pulseoxymeter

Secondary outcomes

1

Description

systolic blood pressure

Timepoint

once before suctioning and another 2 and 5 minute after suctioning

Method of measurement

Monitor

2

Description

diastolic blood pressure

Timepoint

Once before suctioning and another 2 and 5 minute after suctioning

Method of measurement

Monitor

3

Description

mean arterial blood pressure

Timepoint

once before suctioning and another 2 and 5 minute after suctioning

Method of measurement

Monitor

4

Description

pulse rate

Timepoint

once before suctioning and another 2 and 5 minute after suctioning

Method of measurement

Monitor

Intervention groups

1

Description

This study for group A , suctioning is performance once without and once with instillation 5 ml normal saline. the blood pressure, respiratory rate, heart rate, mean airway pressure record (prior to suctioning and after 2 and 5 minute after suctioning). then o2 saturation, ETco2 by pulseoxymeter and capnograph (monitor) record , once before suctioning and another after suctioning (immediately , 15, 30 , 45 second and also 1,2,3,4,5 minute after suctioning).

Category

Treatment - Other

2

Description

This study for group B , suctioning is performance once with instillation 5 ml normal saline and once without . the blood pressure, respiratory rate, heart rate, mean airway pressure record (prior to suctioning and after 2 and 5 minute after suctioning). then o2 saturation, ETco2 by pulseoxymeter and capnograph (monitor) record , once before suctioning and another after suctioning (immediately , 15, 30 , 45 second and also 1,2,3,4,5 minute after suctioning).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational Medical Centers Of Guilan University Of Medical Science (Razi and Poursina Hospital)

Full name of responsible person

Masoumeh Adib

Street address

Rasht- Shahid Beheshti Boulvar-Shahid Beheshti Collage Of Nursing and Midwifery

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University Of Medical Science

Full name of responsible person

Dr Abdoalrasoul Sobhani

Street address

Rasht - Namjoo Ave -Shahid Siadati Ave-deputy of research Building

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan University Of Medical Science

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

Guilan University Of Medical Science

Full name of responsible person

Masoumeh Adib

Position

M.S/Faculty Of Member

Other areas of specialty/work

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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