Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of two levels of negative pressure in open endotracheal tube suction on physiological indices among patients in intensive care units of Al-Zahra Hospital, Isfahan in 2013

Protocol summary

Summary

Comparison the effect of two levels of negative pressure in open endotracheal tube suction on physiological indices among patients in intensive care units of Al-Zahra Hospital, Isfahan in 2013, Study design: Randomized clinical trial with parallel design, Study population: patients admitted to the intensive care unit at Al-Zahra Hospital, Major inclusion criteria:minimum age 18 years and maximum age 75 years, having endotracheal tube and conect to ventilatore, no coagulation disordere and thrombocytopenia, having stable hemodynamice before suctioning(SBP>100,HR<120,MAP>70) and no hypoxemia(SPO2<90).Major inclusion criteria: age over than 18; obtaining informed consent; no blood clotting disorders; no chronic respiratory disease; intubation time between 48 hours and one week. Major exclusion criteria: extubation during the study; become unstable hemodynamic parameters such as bradycardia, arrhythmia, cyanosis, loss of arterial oxygen.sample size:60, Intervention or interventions: First group suctioned with negative pressure of 100 mmHg and second group with 200 mmHg. Time of intervention:suction with negative pressure 100 and 200mmHg will be perfomed for each group and Design variables will be taken immediately before, during, 5 and 20 minute after endotracheal suctioning in both groups. Primary outcomes: changes in physiological indices

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041713039N1**
Registration date: **2013-07-26, 1392/05/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-07-26, 1392/05/04

Registrant information

Name
Hojatollah Yousefi
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3792 7543
Email address
yousefi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2013-04-11, 1392/01/22

Expected recruitment end date

2013-05-24, 1392/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of two levels of negative pressure in open endotracheal tube suction on physiological indices among patients in intensive care units of Al-Zahra Hospital, Isfahan in 2013

Public title

Comparison the effect of two levels of negative pressure in open endotracheal tube suction on physiological indices among patients in intensive care units of Al-Zahra Hospital, Isfahan in 2013

Purpose

Supportive

Inclusion/Exclusion criteria

Major inclusion criteria: age over than 18; obtaining informed consent; no blood clotting disorders; no chronic respiratory disease; intubation time between 48 hours and one week. Major exclusion criteria: extubation during the study; become unstable hemodynamic parameters such as bradycardia, arrhythmia, cyanosis, loss of arterial oxygen

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Isfahan University of Medical sciences

Street address

Isfahan University of Medical Sciences, Azadi Square, Hezar-Jerib Street, Isfahan. Postal cod: 81746-73461

City

Isfahan

Postal code

81746-73461

Approval date

2013-04-09, 1392/01/20

Ethics committee reference number

392012

Health conditions studied

1

Description of health condition studied

Respiratory conditions due to other specified external agents

ICD-10 code

J70.8

ICD-10 code description

Respiratory conditions due to other specified external agents

Primary outcomes

1

Description

Spo2

Timepoint

Immediately before, During, 5 and 20 min after endotracheal suctioning

Method of measurement

Vital signs monitor

Secondary outcomes

1

Description

Heart Rate

Timepoint

Immediately before, During, 5 and 20 min after endotracheal suctioning

Method of measurement

Vital signs monitor

2

Description

MAP

Timepoint

Immediately before, During, 5 and 20 min after endotracheal suctioning

Method of measurement

Vital signs monitor

3

Description

SBP

Timepoint

Immediately before, During, 5 and 20 min after endotracheal suctioning

Method of measurement

Vital signs monitor

4

Description

DBP

Timepoint

Immediately before, During, 5 and 20 min after endotracheal suctioning

Method of measurement

Vital signs monitor

5

Description

Respiratory Rate(RR)

Timepoint

Immediately before, 5 and 20 min after endotracheal suctioning

Method of measurement

Vital signs monitor

Intervention groups

1

Description

this study is a parallel study that First group suctioned with negative pressure of 100 mmHg with standard method

Category

Prevention

2

Description

Scond group suctioned with negative pressure of 200 mmHg with standard method

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital, Intensive Care Units

Full name of responsible person

Jahanbakhsh Vahdatnejad (student of MSc in critical care nursing)

Street address

Al-Zahra Hospital, Sofeh Avenue, Isfahan. Postal cod: 81746-75731

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Peiman Adibi

Street address

Isfahan University of Medical Sciences, Azadi Square, Hezar-Jerib street, Isfahan. Postal cod: 81746-73461

City

Isfahan

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, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Jahanbakhsh Vahdatnejad

Position

student of MSc in critical care nursing

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Azadi Square, Hezar-Jerib street, Isfahan. Postal cod: 81746-73461

City

Isfahan

Postal code

73461-81746

Phone

+98 31 1792 2944

Fax

Email

yousefi@nm.mui.ac.ir;jahan_vahdat@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Yousefi Hojatollh

Position

PHD

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Azadi Square, Hezar-Jerib street,

Isfahan. Postal cod: 81746-73461

City

Isfahan

Postal code

73461-81746

Phone

+98 31 1792 2944

Fax

Email

yousefi@nm.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Jahanbakhsh Vahdatnejad

Position

student of MSc in critical care nursing

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Azadi Square, Hezar-Jerib

City

Isfahan

Postal code

73461-81746

Phone

+98 31 1792 2944

Fax

Email

yousefi@nm.mui.ac.ir

Web page address

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