

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparing the effect of open and closed endotracheal suctioning on hemodynamic indices, oxygen saturation, and pain in post CABG patients under mechanical ventilation.

Protocol summary

Summary

The main objective of this study is comparing the effect of open and closed endotracheal suctioning on hemodynamic indices, oxygen saturation and pain in post CABG patients under mechanical ventilation. Design: 150 patients who needed endotracheal suctioning in CSICU following CABG were randomly allocated to undergo either closed (n=75) or open (n=75) suctioning. After getting oxygenated with 100% O2 for one minute, the patients are suctioned with either methods for 15 seconds. They will also receive 100% oxygen for one minute after suctioning. Pain score using critical pain objective tool (CPOT) is compared during suctioning between two groups. Mean arterial pressure, heart rate and peripheral oxygen saturation are compared after suctioning at one minute intervals for 5 minutes between two groups. This study is single-blind, parallel clinical trial. Inclusion criteria: Patients without primary lung pathophysiology; lack of dysrhythmia; Age more than 18; Hemodynamic stability; lack of intracranial hypertension; PEEP<10 CMH2O; FIO2<60%; PFRatio>200; RASS = 0, -1 Exclusion criteria: Any serious adverse effects during study. Intervention: In one group closed suction method and in another open suction method will perform. Main outcome measures: Severity of pain, for Pain score, using critical pain objective tool (CPOT) that is measured during suctioning.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042713134N1**
Registration date: **2013-06-16, 1392/03/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-16, 1392/03/26

Registrant information

Name

Sahereh Mirzaei

Name of organization / entity

Gonabad university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 53 3722 3514

Email address

mirzaei.s@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Gonabad university of medical sciences.

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-08-06, 1392/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of open and closed endotracheal suctioning on hemodynamic indices, oxygen saturation, and pain in post CABG patients under mechanical ventilation.

Public title

Comparing the effect of open and closed endotracheal suctioning on mean arterial pressure, heart rate, oxygen saturation, and pain in post CABG patients under mechanical ventilation.

Purpose

Supportive

Inclusion/Exclusion criteria

Major Inclusion criteria: Patients without primary lung pathophysiology; lack of dysrhythmia; Age more than 18 years old; Hemodynamic stability; lack of intracranial hypertension; PEEP<10 CMH2O; FIO2<60%; PFRatio>200; RASS = 0, -1 Exclusion criteria: Any serious adverse effects during study such as; new cerebral side effects; dangerous dysrhythmia; Drop of oxygen saturation during suctioning.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

Research Ethics Committee of Gonabad university of medical sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

City

Gonabad

Postal code

Approval date

2013-03-03, 1391/12/13

Ethics committee reference number

91/5/7

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Severity of Pain

Timepoint

Before and during suctioning

Method of measurement

CPOT

Secondary outcomes

1

Description

Mean arterial pressure

Timepoint

Before and immediately after suctioning and then every minute up to five minutes

Method of measurement

Observation and record

2

Description

Pao2

Timepoint

Before and immediately after suctioning and then every minute up to five minutes

Method of measurement

Observation and record

3

Description

Heart rate

Timepoint

Before and immediately after suctioning and then every minute up to five minutes

Method of measurement

Observation and record

4

Description

Spo2

Timepoint

Before and immediately after suctioning and then every minute up to five minutes

Method of measurement

Observation and record

5

Description

Paco2

Timepoint

Before and immediately after suctioning and then every minute up to five minutes

Method of measurement

Observation and record

6

Description

Bronchospasm

Timepoint

Before and immediately after suctioning and then every minute up to five minutes

Method of measurement

Observation and records

7

Description

Arrhythmia

Timepoint

Before and immediately after suctioning and then every minute up to five minutes

Method of measurement

Observation and record

Intervention groups

1

Description

After getting oxygenated with 100% O2 for one minute, the patients are suctioned with closed suction method for 15 seconds. The catheter will insert into the endotracheal tube until resistance meet and withdraw 0.5 cm. A negative pressure of maximum 20 KPa will set, and catheter will withdraw. They will also receive 100% oxygen for one minute after suctioning.

Category

Prevention

2

Description

After getting oxygenated with 100% O2 for one minute, the patients are suctioned with open suction method for 15 seconds. The catheter will insert into the endotracheal tube until resistance meet and withdraw 0.5 cm. A negative pressure of maximum 20 KPa will set, and catheter will withdraw while gently rotating. They will also receive 100% oxygen for one minute after suctioning.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Dr. Shahram Amini

Street address

CSICU, Imam Reza Hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Gonabad university of medical sciences

Full name of responsible person

Dr. Ali Mohammad pour Vice chancellor for research, Gonabad University of Medical Sciences

Street address

Jadeye Asiaee

City

Gonabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of Gonabad 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

Gonabad university of medical sciences

Full name of responsible person

Sahereh Mirzaei

Position

Student of master degree in critical care nursing / Nurse

Other areas of specialty/work

Street address

Asiaee road

City
Gonabad
Postal code
Phone
+98 53 3722 3028
Fax
Email
sahereh_mirzaei@yahoo.com, mirzaei.s@gmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad university of medical sciences
Full name of responsible person
Dr. Shahram Amini
Position
ICU fellowship
Other areas of specialty/work
Street address
Imam Reza hospital, Imam Reza square, Ibn sina street
City
Mashhad
Postal code
Phone
+98 51 1852 5208
Fax
Email
aminish@mums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Gonabad university of medical sciences
Full name of responsible person
Sahereh Mirzaei
Position
Student of master degree in critical care nursing / Nurse
Other areas of specialty/work
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi
City
Gonabad
Postal code
Phone
+98 53 3722 3028
Fax
+98 53 3722 3814
Email
sahereh_mirzaei@yahoo.com, mirzaei.s@gmu.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