

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The Effect of Mechanical Cough Assist Device on Respiratory and Hemodynamic Parameters in Patients With Respiratory Disorder After Heart Surgery

Protocol summary

Study aim

the effect of mechanical cough aid on respiratory parameters and Hemodynamics of patients with respiratory disorders after open heart surgery

Design

randomized controlled clinical trial..84 patients with open heart surgery regular randomly Block size six, Two groups: (intervention) and control

Settings and conduct

Adult ICU of Shahid Rajaei Cardiovascular Hospital, after receiving routine of respiratory physiotherapy . intervention once in the morning after surgery and once on the third day. Respiratory and hemodynamic indices measured, 2 hours ago, 2,8, 14, 24 hours after study the second day ,2 hours after the second n on The third days, Chest x-ray before, after 24 hours later , the amount of exhaled air (PFM) before, 2 hours after the first intervention, and 2 hours after the second intervention.

Participants/Inclusion and exclusion criteria

respiratory distress, first minute expiratory volume less than 80%, age 30-85 years, body mass index less than 35, cardiopulmonary pump less than 160 minutes, left ventricular ejection fraction more than 25%, non-dialysis, no history of tumor in Chest and thoracic surgery. Do not admit patients for whom any additional intervention is prohibited by the doctor and who suspected to be Quid-19.

Intervention groups

Cough aid is performed in the morning after surgery, once on the second day and once on the third day.

Main outcome variables

Respiratory indicators (BLOOD GAS), Hemodynamic parameters (systolic blood pressure, diastolic blood pressure, respiratory rate and number Heart rate) and the presence or absence of atelectasis and is measurement PFM.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201105049280N1**

Registration date: **2022-01-18, 1400/10/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-18, 1400/10/28**

Update count: **0**

Registration date

2022-01-18, 1400/10/28

Registrant information

Name

Tahereh Abolghasemi

Name of organization / entity

Center of academic investigative cardio vascular of Shaid Rajaie

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Mechanical Cough Assist Device on Respiratory and Hemodynamic Parameters in Patients With Respiratory Disorder After Heart Surgery

Public title

The Effect of Mechanical Cough Assist Device on Respiratory and Hemodynamic Parameters in Patients With Respiratory Disorder After Heart Surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients recovered after heart surgery • Patients with respiratory disorder, PFT<80 Patients aged 30-85 years Patients with morbid obesity (body mass index 35 and less than 35 kg / m2) Patients with a cardiopulmonary pump duration of 160 minutes or less Patients with left ventricular ejection fraction greater than 25% • Non-dialysis patients Patients without a history of thoracic and thoracic surgery

Exclusion criteria:

Patients with Quid-19 diagnosis Patients for whom any additional intervention is prohibited by the doctor's order.

AgeFrom **30 years** old to **85 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **84****Randomization (investigator's opinion)**

Randomized

Randomization description

The study is a randomized controlled clinical trial. 84 patients with open heart surgery Who are eligible for inclusion in the study And randomly block size Six . They are divided into two groups (intervention) and control through a computer CREATE A PANDOMISATION LIST that has an equal number of each group in each block. Like this(ABABBA ,ABABBA ,ABBABA,)

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**<https://ethics.research.ac.ir/PortalCommittee>.**Street address**

Tehran, District 3, Tehran, Valiasr St., at the beginning of Niayesh Highway, Ayatollah Hashemi Rafsanjani Highway,

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2021-10-02, 1400/07/10

Ethics committee reference number

IR.RHC.REC.1400.072

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

Ooen heart surgery, Coronary by pass graft

ICD-10 code

I25.710

ICD-10 code description

Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris

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

Respiratory indicators (blood gases), (PH, SPO₂, PO₂, PCO₂, HCO₃, BE)

Timepoint

Before intervention, 2 hours, 8 hours, 14 hours and 24 hours after the first intervention and 2 hours after the second intervention.

Method of measurement

The measurement was performed using a techno-media device.

2**Description**

Hemodynamic parameters (systolic blood pressure, diastolic blood pressure, respiration rate and heart rate)

Timepoint

Before intervention, 2 hours, 8 hours, 14 hours and 24 hours after the

Method of measurement

Measurements were performed using a cardiac monitoring device.

3

Description

Presence or absence of atelectasis

Timepoint

قبل و 2 ساعت بعد از مداخله اول ونوبت دوم بعد از مداخله دوم

Method of measurement

Observation chet X-Ray

Secondary outcomes

empty

Intervention groups

1

Description

In Intervention group: after extubated inThe first day after of receiving routine daily physiotherapy ,used mini Pegaso cough with made in the country Italy with 2 mode percusure and automatic . They receivele through a face mask 3-5 times of the first day and repeted 3 times of the second days. hemodynamic symptoms and blood gases before and 2,8,14,24 hours after the intervention of the first day and 2 hours After the second days intervention, it is measured in both groups. peack flow meterhow (measure air flows from lungs) before the intervention and 2 hours after the intervention, the first and second days are measured for 2 groups. Presence or absence of atelectasis Checked before intervention and 2hours after intervention by chest xray.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Cardiovascular Research Training Center محسن

Full name of responsible person

Mohsn Ziyfard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Rajaie Cardiovascular, Medical and Research Center

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

Iran University of Medical Sciences

Full name of responsible person

Mohsen Ziyaefard

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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