

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the Effectiveness of Nursing Care Bundles with Routine Care on the Outcomes of Chest Tube Drainage in Patients Undergoing Open Heart Surgery

Protocol summary

Study aim

determine the Effects of Nursing care bundles on the outcomes of chest tubes drainage in patients undergoing cardiac surgery

Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct

Patients undergoing open heart surgery in the cardiac care unit of Baqiyatallah hospital Samples are selected by available sampling method and then randomly divided into intervention and control groups. The control group received no intervention and routine procedure was performed. But in the intervention group the care package is administered and the requested information is recorded in the checklist Blindness is one-way

Participants/Inclusion and exclusion criteria

- 1) Inclusion criteria are to be included in the study: Willingness to Participate in the Study, Age Range 18 and Under 70 Years, Elective Open Heart Surgery (Elective) and Left Ventricular Ejection Fraction Greater than 30%.
- 2) exclusion criteria are to be included: High-dose inotropic intake, Re-surgery, Previous coagulation problems and Has Renal failure.

Intervention groups

In the control group, no intervention was performed and usual and routine procedures were done. In the intervention group the care package is administered and the requested information is recorded in the checklist. Package includes the appropriate height of a patient bed, respiratory training and piping to mechanical ventilation drainage connection to suction

Main outcome variables

The main outcomes are: Atelectasis, Pleural effusion, Pericardial effusion, Arterial blood gases, Drainage.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200114046124N1**

Registration date: **2020-05-23, 1399/03/03**

Registration timing: **retrospective**

Last update: **2020-05-23, 1399/03/03**

Update count: **0**

Registration date

2020-05-23, 1399/03/03

Registrant information

Name

HamidReza Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2244 1099

Email address

hra9908@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Nursing Care Bundles with Routine Care on the Outcomes of Chest Tube Drainage in Patients Undergoing Open Heart Surgery

Public title

The Effect of Nursing Care Bundles on the Outcomes of Chest Tube Drainage in Patients Undergoing Open Heart Surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to Participate in the Study Age Range 18 and Under 70 Years Elective Open Heart Surgery (Elective) Left Ventricular Ejection Fraction Greater than 30%

Exclusion criteria:

High-dose inotropic intake Re-surgery Previous Coagulation Disorders Has Renal failure

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

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

Single blinded

Blinding description

Given that the participants in this study (patients) were unaware of the study group (intervention and control), on the other hand, the group of evaluators (anesthesiologist) to reduce the bias related to the intervention and evaluation of the consequences and its possible impact on The results of the study were also unknown to the study group. But given the awareness of other members of the research team about the nature of the intervention and the study groups, the study is ultimately single blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Ethics committee of Baqiyatallah University of Medical Sciences, After Sheikh Bahayi Street, Mulla Sadra Street, Vanak Square

City

Tehran

Province

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Postal code

1698749511

Approval date

2019-11-12, 1398/08/21

Ethics committee reference number

IR.BMSU.Rec.1398.272

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

Patients with valve coronary artery disease or both of them

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

Percentage of patients with atelectasis, pleural effusion and pericardial effusion

Timepoint

After open heart surgery and entering the cardiac care unit until being transferred from the ward

Method of measurement

checking chest x-ray and clinical signs of patients by Anesthesiologist

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Perform routine actions in the section without additional work

Category

N/A

2**Description**

Intervention group: Care bundles consisting of ; 1- the appropriate height to the bed so that the pipes are not hung from the bed and can be used to maximize Gravity Drainage 2-Using a suitable mechanical ventilation pip

Zinc number 5 and after separation using deep breathing exercises and effective coughing 3-Binding of pipes to Ganco suction

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Al'Azam Hospital

Full name of responsible person

Mr. Ali Samadinia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hamidreza Azizi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

regarding to research findings (research outcomes), the
lecture will be delivered in scientific form as appropriate
in the scientific community.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Public access

Under which criteria data/document could be used

Access is free if the source is mentioned

From where data/document is obtainable

Article Papers and Research Team Researcher: Hamid
Reza Azizi Email: hra9908@gmail.com Phone:
09120441360

What processes are involved for a request to access data/document

By replying to incoming emails

Comments