Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Incentive Spirometer on The Prevention of Postoperative Pulmonary Complications following Cardiac Surgeries

Protocol summary

Study aim

I.To determine the effect preoperative use of an Incentive Spirometer has on preventing postoperative pulmonary complications among cardiac surgical patients. III.To determine the demographic and clinical factors associated with increased risk for the development of postoperative pulmonary complications following cardiac surgeries.

Design

Interventional, prospective, randomized

Settings and conduct

The study will be conducted in three centers in the city of Baghdad, including Ibn Al-Nafees Cardiology Hospital, Iraqi center for heart diseases, Ibn Al-Bitar center for cardiac surgery

Participants/Inclusion and exclusion criteria

 Inclusion criteria: Patients who will agree to participate in the study based on their informed consent. Patients who undergo open heart surgery including (coronary and valvular) procedures Exclusion criteria: thoracic, abdominal, or cerebral aneurysms Recent cardiothoracic or abdominal surgery.

Intervention groups

Patients allocated to the intervention group were trained to use the IS, they were asked to maintain sitting position, hold the IS in an upright position, place the lips tightly around the mouthpiece and perform slow and deep inhalation in order to raise the balls in the chambers one by one gradually to set the target of 1.200 cc. At maximum inhalation, the mouthpiece is removed, followed by a breath-hold and normal exhalation. Patients were asked to repeat the maneuver in a set of ten times hourly while awake until the day of the surgical operation.

Main outcome variables

Primary outcomes: The incidence of postoperative pulmonary complications, which are scored by a pulmonologist who is blinded to patients' allocation

General information

Reason for update

The reason for update is to edit some information regarding the sample age , inclusion criteria and recruitment dates, randomization and blinding

Acronym

IST

IRCT registration information

IRCT registration number: **IRCT20211224053503N1**
Registration date: **2022-01-04, 1400/10/14**
Registration timing: **prospective**

Last update: **2022-06-10, 1401/03/20**
Update count: **2**

Registration date

2022-01-04, 1400/10/14

Registrant information

Name

Jadeel Noor

Name of organization / entity

The University of Baghdad

Country

Iraq

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-04-01, 1401/01/12

Actual recruitment start date

2022-01-09, 1400/10/19

Actual recruitment end date

2022-04-01, 1401/01/12

Trial completion date

empty

Scientific title

Effectiveness of Incentive Spirometer on The Prevention of Postoperative Pulmonary Complications following Cardiac Surgeries

Public title

Preoperative Incentive Spirometer Breathing Exercise to Prevent Postoperative Pulmonary Complications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who will agree to participate in the study based on their informed consent . Subjects with age >50 years. Patients who undergo open heart surgery including (coronary and valvular) procedures

Exclusion criteria:

Patients who refuse to participate in the study. Patients who have thoracic, abdominal, or cerebral aneurysms recent cardiothoracic or abdominal surgery.

Age

From **50 years** old to **79 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **128**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Parallel group trials design was used, in which subjects were randomly assigned to study group and control group. Unit of randomization : Individual Simple randomization technique was used for the assignment of subjects into a particular group. flipping a coin method was chosen (heads - control, tails - intervention).

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is single-blinded, since the participants are intentionally kept unaware of which of the two groups (study and control groups) they have been assigned

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Approval Committee, at the College of Nursing

Street address

Bab AL-Muadum

City

Baghdad

Postal code

10001

Approval date

2021-12-08, 1400/09/17

Ethics committee reference number

2395

Health conditions studied

1

Description of health condition studied

Postoperative pulmonary complications

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The incidence of postoperative pulmonary complications

Timepoint

Subjects response to the intervention will be within one week of the first meeting to examine the effectiveness of the intervention on preventing pulmonary complications

Method of measurement

Diagnosis of pulmonary complications from patients' records, results of Peak Expiratory Flow Rate and Arterial Blood Gases

Secondary outcomes

1

Description

Peak Expiratory Flow Rate (PEFR)

Timepoint

Secondary outcome is measured before and after the application of intervention within one week

Method of measurement

Data will be obtained from patient's records

2

Description

Arterial Blood Gases

Timepoint

Secondary outcome is measured before and after the

application of intervention within one week

Method of measurement

Data will be obtained from patient's records

3

Description

Hospital length of stay

Timepoint

Secondary outcome is measured after the application of intervention within one week

Method of measurement

Data will be obtained from patient's records

4

Description

Oxygen dependency

Timepoint

Secondary outcome is measured after the application of intervention during the postoperative phase

Method of measurement

Observation, medical records

5

Description

Intensive Care Unit stay

Timepoint

Secondary outcome is measured after the application of intervention during the postoperative phase in the intensive care unit

Method of measurement

Data will be obtained from patient's records

6

Description

Prolonged ventilation

Timepoint

Secondary outcome is measured after the application of intervention during the postoperative phase in the intensive care unit

Method of measurement

Data will be obtained from patient's records

Intervention groups

1

Description

Intervention group: The starting point of the intervention phase will start by instructing patients undergoing open heart surgeries to use Incentive Spirometer (IS) which is a mechanical device that provides patients with visual reinforcement to inhale in a deep and slow manner to enhance lungs reinflation which treat or prevent atelectasis, intervention group will use the IS hourly while awake for two days prior to surgery .The intervention group will be observed for 7 days to see the influence of the given intervention on preventing pulmonary complications.

Category

Treatment - Devices

2

Description

Control group: Control group will not use Incentive Spirometer(IS) before surgery ,instead they will receive the standard usual care provided by health care professionals. Control group will be be observed for 6 days to compare the incidence of postoperative pulmonary complications with those of the intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iraqi center for heart diseases

Full name of responsible person

Jadeel Al-Tuwaij

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2

Recruitment center

Name of recruitment center

Ibn Al-Bitar center for cardiac surgery

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3

Recruitment center

Name of recruitment center

Ibn Al-Nafees Cardiology Hospital

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
College of Nursing, University of Baghdad
Full name of responsible person
Professor Huda Baqer Hassan, PhD. Dean
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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
The author of the trial is the funding source
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
College of Nursing, University of Baghdad
Full name of responsible person
Jadeel Al-Tuwaij
Position
Student
Latest degree
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not 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
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The researcher is acknowledging the scientific community to have verifiable findings of the study. sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals.
When the data will become available and for how long
God willing, once finishing the process of data collection, analysis and successfully publishing the manuscript, all the related files will become available for 6 months after publications
To whom data/document is available
All the related files will be shared with any scientific interested parties.
Under which criteria data/document could be used
It may be used after seeking the author's permission and acknowledging his contribution.
From where data/document is obtainable
The author's professional e-mail that will be available with the published manuscript can be used to contact the author. e-Mail: jadeel.nour1202a@conursing.uobaghdad.edu.iq
What processes are involved for a request to access data/document
N/A
Comments
Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfilling their academic endeavors