Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Incentive Spirometry and Respiratory Physiotherapy on Improving Respiratory Function in Patients Following Chest Injuries

Protocol summary

Study aim

The effect of incentive spirometry and respiratory physiotherapy on improving respiratory function in patients after chest injury

Design

Clinical trial with control group; single-blind; randomized; on 64 patients; Random allocation software version 2 was used for randomization

Settings and conduct

After selection, demographic characteristics of patients were collected. The primary goals of this study included changes and results of PFT that were performed on all patients at the end of the third day of the study. the assessment of the patient's oxygenation status was recorded each time before and after the intervention. In the intervention group, both incentive spirometry and respiratory physiotherapy were used, while in the control group, only respiratory physiotherapy exercises were performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18-65 years, consciousness, injury severity score ≥11, non-penetrating injury with rib fracture ≥1 Exclusion criteria: unwillingness to participate, loss of consciousness level <14, chronic obstructive pulmonary disease, asthma, history of heart disease, venous obstruction, coagulation problems after abdominal, thoracic, brain and eye surgery

Intervention groups

The correct method of incentive spirometry involves placing the patient in a semi-sitting position and maintaining a deep breath for a maximum of 2 to 3 seconds and then exhaling. This process was performed daily for at least one hour for three consecutive days, 10 times a day in the intervention group. Respiratory physiotherapy exercises were performed under supervision of two trained nurses in both groups. In the comparison group, incentive spirometry wasn't performed

Main outcome variables

Pulmonary oxygen saturation (SpO2), and ABG status including pH, pO2 and pCO2, and FVC; FEV1; (FEV1/FVC) before and after the intervention between control and intervention group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250210064698N1**
Registration date: **2025-04-18, 1404/01/29**
Registration timing: **retrospective**

Last update: **2025-04-18, 1404/01/29**
Update count: **0**

Registration date

2025-04-18, 1404/01/29

Registrant information

Name

Firoozeh Abolhasanizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 398 4679

Email address

firoozeh1981@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

2023-04-30, 1402/02/10

Actual recruitment end date
2024-01-20, 1402/10/30
Trial completion date
empty

Scientific title
The Effect of Incentive Spirometry and Respiratory Physiotherapy on Improving Respiratory Function in Patients Following Chest Injuries

Public title
The effect of chest physiotherapy on respiratory function after chest trauma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients admitted to Shahid Bahonar Hospital in Kerman with chest injuries and requiring chest intubation during the study period in 1402 Age range between 18 and 65 years Be alert with GCS 15 The maximum injury severity score is 11. Non-penetrating injury with fracture of more than one rib
Exclusion criteria:
Unwillingness to participate in the study Decreased alertness Chronic obstructive pulmonary disease and asthma History of heart disease Venous obstruction Coagulation problems after abdominal and thoracic or brain and eye surgery
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **64**
Actual sample size reached: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a restricted randomization method of block randomization with a ratio of 1:1 and a block size of four was used. Random allocation software version 2.0 was used to randomize the samples. In addition to simple randomization, this software was able to generate a random sequence using the block method, and as a result, this software was used for randomization simultaneously with blocking the samples. In order to maintain homogeneity of sample distribution and the frequency of chest injuries (penetrating and non-penetrating), the control and intervention groups included 18 patients with non-penetrating injuries and 14 patients with penetrating injuries to the chest.
Blinding (investigator's opinion)
Single blinded
Blinding description
In order to blind the study, a statistician independent of the study was responsible for the random assignment of participants to each of the two groups and the final analysis of the data. As a result, one-way blinding was utilized in this study.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Shadid Bahonar Hospital
City
kerman
Province
Kerman
Postal code
7613747181
Approval date
2023-04-26, 1402/02/06
Ethics committee reference number
IR.KMU.AH.REC.1402.012

Health conditions studied

1

Description of health condition studied
lung contusion
ICD-10 code
S27.32
ICD-10 code description
Contusion of lung

2

Description of health condition studied
rib fracture
ICD-10 code
S22.4
ICD-10 code description
Multiple fractures of ribs

3

Description of health condition studied
pneumothorax
ICD-10 code

S27.0

ICD-10 code description

Traumatic pneumothorax

4

Description of health condition studied

hemothorax

ICD-10 code

S27.1

ICD-10 code description

Traumatic hemothorax

Primary outcomes

1

Description

blood oxygen saturation

Timepoint

Before and after the three-day intervention (days one and three)

Method of measurement

ABG laboratory test

Secondary outcomes

1

Description

Hemothorax; pneumothorax; atelectasis; pneumonia

Timepoint

Third day after the intervention

Method of measurement

Spiral Chest CT-Scan

2

Description

Arterial pressure of O2 (PaO2)

Timepoint

Before and after the three-day intervention (days one and three)

Method of measurement

ABG laboratory test

3

Description

Arterial pressure of CO2 (PaCO2)

Timepoint

Before and after the three-day intervention (days one and three)

Method of measurement

ABG laboratory test

4

Description

Arterial blood pH

Timepoint

Before and after the three-day intervention (days one and three)

Method of measurement

ABG laboratory test

5

Description

FVC

Timepoint

Before and after the three-day intervention (days one and three)

Method of measurement

Pulmonary function test

6

Description

FEV1

Timepoint

Before and after the three-day intervention (days one and three)

Method of measurement

Pulmonary function test

7

Description

FEV1/FVC

Timepoint

Before and after the three-day intervention (days one and three)

Method of measurement

Pulmonary function test

Intervention groups

1

Description

Intervention group: The correct method of incentive spirometry involves placing the patient in a semi-sitting position and maintaining a deep breath for a maximum of 2 to 3 seconds and then exhaling. This process was performed daily for at least one hour for three consecutive days, 10 times a day in the intervention group. Respiratory physiotherapy exercises along with deep breathing were performed based on a fixed schedule and under the supervision of two trained nurses in both groups.

Category

Rehabilitation

2

Description

Control group: Respiratory physiotherapy exercises along with deep breathing were performed based on a fixed schedule and under the supervision of two trained nurses.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Kerman Shahid Bahonar Hospital
Full name of responsible person
Dr. Negar Lotfmohammadi
Street address
Qarni Street, Shahid Bahonar Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Firoozeh Abolhasanizadeh
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Beginning of Haft Bagh Alavi Avenue, University of Medical Sciences Campus
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Web page address
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Firoozeh Abolhasanizadeh
Position
associated professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Latest degree
Specialist
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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data from the study, study protocol, statistical analysis map, statistical analysis form, patient consent form, clinical study report, and codes used in data analysis were used in the student thesis of Dr. Lotf Mohammadi and the published article at the end of the study, and will be visible on the website of the Department of General Surgery of Kerman University of Medical Sciences in the student theses section after 6 months from the publication of the article.

When the data will become available and for how long

The data access period begins 6 months after the results are published.

To whom data/document is available

The data will be accessible to the public after obtaining permission from the Vice Chancellor for Research and the Ethics Committee of Kerman University of Medical Sciences.

Under which criteria data/document could be used

The data will be available for use by other researchers for statistical analysis and use in other research after obtaining permission from the Vice President for Research and the Ethics Committee of Kerman University of Medical Sciences.

From where data/document is obtainable

To receive the data, an electronic letter should be sent to the Vice Chancellor for Research of the university, and after approval by the Vice Chancellor and the Ethics Committee, to the person in charge of the above research, Dr. Firoozeh Abolhasani, at the email address firoozeh1981@gmail.com, and the data request should be emailed along with the relevant permissions for the data request. People outside the country can contact the university's Vice President for Research by email.

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

To receive the data, an electronic letter should be sent to the Vice Chancellor for Research of the university, and after approval by the Vice Chancellor and the Ethics Committee, to the person in charge of the above research, Dr. Firoozeh Abolhasani, at the email address firoozeh1981@gmail.com, and the data request should be emailed along with the relevant permissions for the data request. People outside the country can contact the university's Vice President for Research by email.

Comments