# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Investigating the effect of breathing and stretching exercises on Oxygen saturation of venous blood, Length of hospitalization and Resilience of patients with chest tubes after chest trauma

## Protocol summary

**Study aim**

Determining the effect of breathing and stretching exercises on venous blood oxygen saturation, length of hospitalization, and resilience of patients with chest tubes after chest trauma

**Design**

This is a randomized controlled clinical trial (with a permutation block design) with two parallel groups and double-blinded.

**Settings and conduct**

This double-blind study includes adult trauma patients (accidents, assaults, falls) hospitalized in emergency and special wards of Shahid Rajaee and Namazi Hospitals, Shiraz University.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Participants must be aware of the place, time, and person; no history of smoking or drugs; no history of respiratory diseases such as lung cancer, asthma, and chronic obstructive pulmonary disease; ability to perform breathing and stretching exercises; willingness to participate in the study. Exclusion criteria: severe head, spinal cord, or abdominal injuries in the same trauma; patients with medical contraindications to chest tube removal, such as persistent air leaks or severe hemothorax; psychiatric disorders (psychosis, major depression, bipolar disorder, and Alzheimer's disease reported by the patient or caregiver); patients who are pregnant or breastfeeding.

**Intervention groups**

Intervention: A researcher and physiotherapist will conduct breathing and stretching exercises three times daily for three days. Control: A chest trauma group with a unilateral chest tube will receive standard treatment. Blood oxygen saturation, resilience (questionnaire), and hospitalization duration will be measured before, one day after, and three days post-intervention.

**Main outcome variables**

blood oxygen saturation, hospitalization duration, and patient resilience

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20241101063561N3**
Registration date: **2025-02-02, 1403/11/14**
Registration timing: **prospective**

Last update: **2025-02-02, 1403/11/14**
Update count: **0**

**Registration date**

2025-02-02, 1403/11/14

**Registrant information**

**Name**
khatereh rostami
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-02-19, 1403/12/01

**Expected recruitment end date**

2025-04-19, 1404/01/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of breathing and stretching exercises on Oxygen saturation of venous blood, Length of hospitalization and Resilience of patients with chest tubes after chest trauma

**Public title**

Investigating the effect of breathing and stretching exercises on Oxygen saturation of venous blood, Length of hospitalization and Resilience of patients with chest tubes after chest trauma

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Adult patients aged 18 to 40 years with a unilateral chest tube after chest trauma Participants should be aware of place, time, and person No history of smoking or other drug use Absence of respiratory diseases such as lung cancer, asthma, and chronic obstructive pulmonary disease Ability to perform breathing and stretching exercises Willingness to participate in research

**Exclusion criteria:**

Severe head, spinal cord, or abdominal injuries in the same trauma Patients who have medical contraindications to chest tube removal, such as persistent air leaks or severe pneumothorax Having a mental disorder (psychosis, major depression, bipolar disorder, and Alzheimer's disease, as reported by the patient or the patient's companion) Patients who are pregnant or breastfeeding

**Age**

From **18 years** old to **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**

Target sample size: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the present study, the permutation block method will be used to collect the sample. Random allocation by permutation block method is listed in 7 blocks of 12 with Random Allocation Software. The statistical consultant of the Faculty of Nursing and Midwifery of Shiraz University of Medical Sciences determines the random allocation sequence and the researcher (student) enters the participants and allocates them to the intervention group based on the entry and exit criteria. In order to conceal, there will be no physical contact between the participants using the distribution method and training the participants at different times to prevent bias.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the person collecting the data and the person analyzing the data are blinded to the groups until the end of the work.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committees of Schools of Nursing and Midwifery, Management and Medical Information s

**Street address**

Hazrat Fatemeh College of Nursing and Midwifery, Entrance to Namazi Hospital, Namazi Square, Shiraz, Fars Province

**City**

Shiraz

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**Postal code**

7193613119

**Approval date**

2024-09-28, 1403/07/07

**Ethics committee reference number**

IR.SUMS.NUMIMG.REC.1403.101

## Health conditions studied

### 1

**Description of health condition studied**

chest trauma

**ICD-10 code**

S27.9

**ICD-10 code description**

Injury of unspecified intrathoracic organ

## Primary outcomes

### 1

**Description**

Venous blood oxygen saturation

**Timepoint**

Before, one and three days after the breathing and stretching exercises intervention

**Method of measurement**

Richter finger pulse oximeter, model Ri-Fox N 1905, for

each patient before, one and three days after chest tube placement (the calibration of the device will be approved by the medical engineering expert of Shahid Rajaee and Namazi Hospital.)

**2**

**Description**
Duration of hospitalization
**Timepoint**
Before, one and three days after the breathing and stretching exercises intervention
**Method of measurement**
The number of days is from the first day of hospitalization to the time of discharge, calculated based on the dates in the patient's hospital record.

**3**

**Description**
Resilience
**Timepoint**
Before, one and three days after the breathing and stretching exercises intervention
**Method of measurement**
The patient's level of resilience in this study is a score obtained from completing the Connor Davidson questionnaire before, one and three days after the intervention. This questionnaire has 25 questions and its aim is to measure the level of resilience in different individuals. To obtain the overall score of the questionnaire, the total scores of all questions are added together, this score will have a range from 0 to 100. The higher this score, the greater the level of resilience of the respondent and vice versa. This questionnaire has been validated in different populations and environments and has good reliability and validity. This questionnaire is completed before, three and seven days after the intervention.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Breathing and stretching exercise programs including chest physiotherapy and pursed lip breathing and motor training interventions such as upper limb motor exercises will be performed at the patient's bedside by the principal investigator and a physiotherapist as a research assistant (a person who has been trained and approved). Professors of the Faculty of Rehabilitation, Shiraz University of Medical Sciences) and an ICU man. Participants will perform these exercises up to 10 times in one hour, depending on their ability and clinical conditions. This activity will be performed three times a day for one hour at 9 am, 3 pm and 9 pm, and the researcher and research assistant will monitor its accuracy. All training will be provided to patients in person and practically. Then, before the intervention, one and three days after the intervention, blood oxygen saturation will be measured and recorded. Also, before, one day after the intervention, and three days after the intervention, a resilience questionnaire will be completed by all patients. The duration of the patients' hospitalization will be assessed and recorded.
**Category**
Rehabilitation

**2**

**Description**
Control group: The control group will be placed under routine care for patients with chest tubes after chest trauma. Then, blood oxygen saturation will be measured and recorded before the intervention, one and three days after the intervention. Also, a resilience questionnaire will be completed by all patients before, one day after the intervention, and three days after the intervention. The duration of hospitalization of the patients will be assessed and recorded. It should be noted that after the end of the study, educational videos on breathing and stretching exercises will also be made available to the control group.
**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Namazi Hospital
**Full name of responsible person**
Ahmad Hossein Zadeh
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Namazi Hospital, Namazi Square, Zand Street, Shiraz, Fars
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**2**

**Recruitment center**
**Name of recruitment center**
Emtyaz Hospital (Rajaee Hospital)
**Full name of responsible person**
Hossein Ali Khalili
**Street address**
Haj Mohammad Esmaeil Imtiaz Hospital and Shahid Rajaee Surgical Emergencies, before reaching Niayesh Boulevard, Shahid Chamran Boulevard,

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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Hamid Mohammadi
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7th Floor, Shiraz University of Medical Sciences Central Building, next to the Red Crescent, Zand Street, Shiraz
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+98 71 3235 7282
**Email**
vcrdep@sums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shiraz 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**
Shiraz University of Medical Sciences
**Full name of responsible person**
Khatereh Rostami
**Position**
Associate Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
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## Person responsible for scientific inquiries

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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**
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**
Yes - There is a plan to make this available

**Title and more details about the data/document**
After the end of the study, it is possible to share the data.

**When the data will become available and for how long**
After the end of the study, it is possible to share data for one year.

**To whom data/document is available**
Researchers working in academic and scientific institutions of medical sciences.

**Under which criteria data/document could be used**
Analysis on documents and data is allowed.

**From where data/document is obtainable**
Dr. Khatereh Rostami is responsible for this project. Phone Number: +98 71 3647 4254 Address: Hazrat Fatemeh College of Nursing and Midwifery, Entrance to Namazi Hospital, Namazi Square, Shiraz, Fars Province Email: khatereh.rostami.nursing@gmail.com

**What processes are involved for a request to access data/document**
In order to access the information of the study, first of all, contact should be made with the manager of this project, Dr. Khatereh Rostami, whose profile is attached below, and then after reviewing the relevant request and meeting the requirements, the documents will be sent as soon as possible. Phone: +98 71 3647 4254 Address: Fars Province, Shiraz, Namazi Square, the entrance of Namazi Hospital, Hazrat Fatima College of Nursing and Midwifery Email: khatereh.rostami.nursing@gmail.com

**Comments**