

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effect of breathing exercises on pain in patients with limb fractures

Protocol summary

Study aim

Effect of breathing exercises on pain in patients with limb fractures

Design

Clinical trial with a control group, with parallel groups, Single blinded, randomized on 100 patients. Sealed Envelope software will be used for randomization.

Settings and conduct

This study will be conducted in the educational center of Valiasr hospital in Arak city. In this intervention, the correct way of diaphragmatic breathing will be explained in a practical way And to measure the pain level of the patients before and after the intervention, a visual pain intensity scale will be used (Visual scale of pain is a 10 cm line, with a score of ten for the most severe pain and a score of zero for no pain). Only the analyzers do not know how the samples are placed in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient should be conscious, The patient has a broken limb, The patient is hospitalized, The patient should be 18-50 years old, The patient does not have a history of drug abuse. Exclusion criteria: The patient has an underlying disease, Patient non-cooperation

Intervention groups

Intervention group: In this group, a 10 cm line is used for the visual scale of pain intensity, where a score of ten is the most severe pain and a score of zero is no pain. Training of diaphragmatic breathing technique in the intervention group is done face to face by the researcher on the day before surgery. Training continues as long as learning occurs, Then the patients are requested to perform the given training 5 times a day and each time for 10 minutes and after that, complete the visual pain measurement scale. Control group: During this period, they do not receive this intervention and only fill out the questionnaire, and their pain intensity is initially measured by the mentioned method.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051142N6**

Registration date: **2022-11-22, 1401/09/01**

Registration timing: **prospective**

Last update: **2022-11-22, 1401/09/01**

Update count: **0**

Registration date

2022-11-22, 1401/09/01

Registrant information

Name

Aida Arjloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0115

Email address

golmehrsherafati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of breathing exercises on pain in patients with limb

fractures

Public title
Effect of breathing exercises on pain in patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The patient should be conscious. The patient has a broken limb. The patient is hospitalized. The patient must be 18-50 years old. The patient does not have a history of drug abuse. The patient should be literate. The patient is already trained.
Exclusion criteria:
 The patient has a history of mental disorder, hearing disorder, and mental retardation. The patient has injuries to the face and thorax. The patient has an addiction. The patient has a history of fibromyalgia, arthritis and rheumatism.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
 Patients are assigned to groups in the order of arrival and based on the randomization sequence that will be generated in advance. This sequence is unpredictable and does not have a specific pattern, and its arrangement is completely random. To assign the samples to two groups, the block randomization method will be used with a block size of 4, so that by using the random number generation software in the block method, the randomization sequence will be produced according to the required sample size for the two groups. First, all the states where two letters A and B can be arranged together in a block of 2 are created, and a block is randomly selected by placing it between the blocks, and from the arrangement pattern in that block for patient allocation is used then this block will be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer will not know how the samples are placed in the intervention and control groups. Other people in the study will be aware of this placement.

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak university of medical sciences

Street address

Arak university of medical sciences, Basij Sq., Sardasht region

City

Arak

Province

Markazi

Postal code

3848176593

Approval date

2022-07-03, 1401/04/12

Ethics committee reference number

IR.ARAKMU.REC.1401.110

Health conditions studied

1

Description of health condition studied

The amount of pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of pain

Timepoint

three days and twice a day (one hour before the intervention and 4 hours after the intervention)

Method of measurement

At the beginning and end of the study, the visual pain scale of interventions is completed by the patients of both groups, and based on this, the pain level of the patients is determined.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, a 10 cm line is used for the visual scale of pain intensity, where a score of ten is the most severe pain and a score of zero is no pain. This visual pain measurement scale is completed by the patient twice a day for three days (one hour before the intervention and 4 hours after the intervention). Training of diaphragmatic breathing technique in the intervention group is done face to face by the researcher on the day before surgery (In such a way that participants are asked to lie on their back with pillows under their head and knees and place one hand on their chest and the other on their stomach. While inhaling, they will move the hand upwards on the abdomen and push the air into the lungs through the nose. While exhaling, they will move the hand down on the stomach and expel the air from the mouth. The other hand will remain motionless on the chest in both cases.), Training continues as long as learning occurs. Then the patients are requested to perform the given training 5 times a day and each time for 10 minutes. At the end, the patients are asked to complete the visual pain scale tool as requested by the researcher.

Category

Other

2

Description

Control group: During this period, they do not receive this intervention and only fill out the questionnaire, and their pain intensity is initially measured by the mentioned method.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Arak educational and therapeutic center

Full name of responsible person

Mehran Azami

Street address

Central Province, Arak, Imam Khomeini St., Valiasr Square

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3819693345

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

DR Alireza Kamali

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University complex of the Great prophet, Basij square, Sardasht

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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

Arak University of Medical Sciences

Proportion provided by this source

80

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

Arak University of Medical Sciences

Full name of responsible person

Mehran Azami

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mehran Azami

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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

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only the part of the data related to the original outcome will be able to be shared.

When the data will become available and for how long

Since the spring of 2023

To whom data/document is available

Researchers and students in this field

Under which criteria data/document could be used

In order to reduce the pain of hospitalized patients

From where data/document is obtainable

Vice chancellor for education and research, Arak university of medical sciences

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

These documents will be available on the website of Arak university of medical sciences.

Comments