

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the effect of rhythmic breathing and progressive muscle relaxation on surgical site pain in patients who are candidates for abdominal hernia surgery

Protocol summary

Study aim

Comparison of the effect of rhythmic breathing and progressive muscle relaxation on surgical site pain in patients who are candidates for abdominal hernia surgery

Design

A clinical trial on 120 patients candidates for abdominal hernia surgery with a control group, one blind and randomized in a block method with a volume of 6

Settings and conduct

This study is conducted on candidates for abdominal hernia in Imam Hossein (AS) Shahroud Hospital. Relaxation and rhythmic breathing techniques are performed in 4 stages after surgery (3, 6, 12, 24 hours after consciousness). The intensity of pain 20 minutes before and after each intervention period is assessed using VAS.

Participants/Inclusion and exclusion criteria

Inclusion criteria: According to the American Society of Anesthesiology (ASA) classification, the patient is in class 1 or 2; Ability to read and write Farsi; Age range from 18 to 75 years. Exclusion criteria: Addiction to drugs and painkillers; Having any psychomotor and cognitive disorder; Having a history of taking sedatives, and painkillers for more than one month, according to the patient's self-report.

Intervention groups

The samples include three groups A progressive muscle relaxation and group B rhythmic breathing and group C control group. The control group will consist of patients who will only receive routine care. The relaxation group relaxes and contracts the muscles according to certain principles for 20 minutes in each session, and in the rhythmic breathing method, patients are asked to close their eyes while lying on their backs, inhale through the nose, and exhale through the mouth. and do this for 20 minutes in each session

Main outcome variables

Postoperative pain score of patients based on VAS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200206046395N2**

Registration date: **2023-01-31, 1401/11/11**

Registration timing: **prospective**

Last update: **2023-01-31, 1401/11/11**

Update count: **0**

Registration date

2023-01-31, 1401/11/11

Registrant information

Name

Mobin Mottahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3233 8090

Email address

mobinmottahedi1372@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-08-11, 1402/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of rhythmic breathing and progressive muscle relaxation on surgical site pain in patients who are candidates for abdominal hernia surgery

Public title
Comparison of the effect of rhythmic breathing and progressive muscle relaxation on surgical site pain in patients who are candidates for abdominal hernia surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 According to the American Society of Anesthesiology (ASA) classification, the patient is in grade 1 or 2 Ability to read and write persian Age range from 18 to 75 years
Exclusion criteria:
 Addiction to drugs and painkillers Having any psychomotor and cognitive disorders Having a history of taking sedatives, painkillers for a period of more than one month according to the patient's self-report

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
In the beginning, all the modes in which 3 letters A, B and C can be put together in a block of 6 are produced and a block is selected randomly and by placing among the blocks. The layout pattern in that block is used to allocate patients

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the study, it is not possible to blind the study participants. However, measures were taken in collecting information. After the intervention, the person collecting the information will not know the type of the participants' group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrood University of Medical Sciences

Street address

Haft Tir Square, Shahrood University of Medical Sciences

City

Shahrood

Province

Semnan

Postal code

3616718473

Approval date

2022-11-02, 1401/08/11

Ethics committee reference number

IR.SHMU.REC.1401.186

Health conditions studied

1

Description of health condition studied

Hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

Postoperative pain score in VAS

Timepoint

3, 6, 12, 24 hours after consciousness after surgery

Method of measurement

VAS visual analog scale

Secondary outcomes

1

Description

Taking painkillers

Timepoint

At 3, 6, 12 and 24 hours after consciousness after surgery.

Method of measurement

check list

Intervention groups

1

Description

Intervention group: Intervention group: Patients in the progressive muscle relaxation intervention group learn how to perform the progressive muscle relaxation technique the day before surgery by using an educational pamphlet and providing oral training by the researcher. The training is provided by the researcher in clear and fluent sentences and. Patients are taught how to relax and contract their 16 main muscle groups according to certain principles, including the muscles of the face, hands, shoulders, legs, back, etc., keeping the muscles contracted for 3 to 5 seconds in all stages. And 10 to 15 seconds are dedicated to rest

Category

Rehabilitation

2

Description

Intervention group: Patients in the rhythmic breathing group learn how to perform the rhythmic breathing technique the day before the operation by using an educational pamphlet and providing oral training by the researcher. This training is provided by the researcher using simple and understandable sentences. The technique is such that the patients are asked to close their eyes while lying on their back, inhale through the nose, then hold their breath and exhale through the mouth, and each time from number 1 to Count 3. All patients in the intervention group are instructed to focus only on inhaling and exhaling air during breathing and are asked to perform rhythmic breathing every five minutes for one minute each time for a period of 20 minutes (a total of four times every 20 minutes).

Category

Rehabilitation

3

Description

Control group: In the control group, no intervention will be done and they will only receive drugs and routine ward care, and only the pain intensity of the patients will be measured and recorded in the above steps.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein (AS) Hospital

Full name of responsible person

Mobin Mottahedi

Street address

Haft Tir Square, Shahrood University of Medical

Sciences

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3233 8090

Email

mobinmottahedi1372@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

Mohammadhasan Imamian

Street address

Haft Tir Square, Shahrood University of Medical Sciences

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3239 5054

Email

pishgiri@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shahrood 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

Shahrood University of Medical Sciences

Full name of responsible person

Mobin Mottahedi

Position

Lecturer

Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Kargar Square - Nawab - Second Thought - No. 21
City
Shahrood
Province
Semnan
Postal code
3618675313
Phone
+98 23 3233 8090
Email
mobinmottahedi1372@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahrood University of Medical Sciences
Full name of responsible person
Mobin Mottahedi
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Kargar Square - Nawab - Second Thought - No. 21
City
Shahrood
Province
Semnan
Postal code
3618675313
Phone
+98 23 3233 8090
Email
mobinmottahedi1372@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahrood University of Medical Sciences
Full name of responsible person
Mobin Mottahedi
Position
Lecturer
Latest degree

Master
Other areas of specialty/work
Nursery
Street address
Kargar Square - Nawab - Second Thought - No. 21
City
Shahrood
Province
Semnan
Postal code
3618675313
Phone
+98 23 3233 8090
Email
mobinmottahedi1372@gmail.com

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

Only part of the data, such as information related to the main outcome, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

If necessary, by contacting Mobin Mottahedi and if there is a logical justification for using it for scientific purposes

From where data/document is obtainable

Mobin Mottahedi, Shahrood, Haft Tir Square, Shahrood University of Medical Sciences; Faculty of paramedicine

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

During a phone call or via e-mail and registering the request and stating the reason and purpose, which is logical and approved, up to two weeks

Comments