

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of diaphragmatic breathing on anxiety, quality of sleep and pain of patients candidate for lumbar discectomy

Protocol summary

Study aim

The effect of diaphragmatic breathing on anxiety, sleep quality and pain in selected patients with lumbar disc surgery

Design

An interventional clinical trial consisted of a group of 35 intervention and a control group of 35, with parallel groups, two blinded by the outcome assessor and the statistical expert, Block randomization

Settings and conduct

This study was a double-blind clinical trial that intervention evaluator and statistical analyzer don't know about intervention and grouping to investigate. This study will be conducted in neurosurgery ward of Vali-asr Hospital. Patients under study will be randomly divided into intervention and control groups, each containing 35 patients. intervention group received diaphragmatic breathing training and will be done one hour before sleep and operation. In the control and intervention groups, the preoperative night anxiety and one hour before the operation, the preoperative sleep quality in the morning of surgery and postoperative pain immediately after the patient is awake will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 years and up, fluency in Persian, no chronic pain, no history of surgery, no addiction, no analgesics in the past 24 hours, mental health, no prior knowledge of diaphragmatic breathing Exclusion criteria: Withdrawal during study, death and possible complications of surgery and anesthesia

Intervention groups

The patients will be randomly divided into intervention and control groups, each containing 35 patients. The intervention group received diaphragmatic breathing training the night before surgery and will be done one hour before bedtime and one hour before enter the operating room . The control group will receive routine care.

Main outcome variables

anxiety, sleep quality, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190426043375N1**

Registration date: **2020-01-29, 1398/11/09**

Registration timing: **prospective**

Last update: **2020-01-29, 1398/11/09**

Update count: **0**

Registration date

2020-01-29, 1398/11/09

Registrant information

Name

yasaman pourandish

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 8967

Email address

y.pourandish@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-09, 1398/11/20

Expected recruitment end date

2020-05-09, 1399/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Effect of diaphragmatic breathing on anxiety, quality of sleep and pain of patients candidate for lumbar discectomy
Public title	Effect of diaphragmatic breathing on anxiety, quality of sleep and pain of patients candidate for lumbar discectomy
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Over 18 years of age fluency in Persian No chronic pain No history of surgery No drug addiction No use of any sedative and analgesics in the past 24 hours mental health Not knowing about diaphragmatic breathing
Exclusion criteria:	Withdrawal from continuing study death possible complications of surgery and anesthesia.
Age	From 18 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Outcome assessor • Data analyser
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	Patients will be selected based on inclusion criteria. Purposeful sampling and then patients are randomly divided into intervention and control groups. In order to comply with the Concealment, the problem of imbalance between the groups is solved by Balanced block randomization with the size of 2, 4 and 6 blocks. These blocks will then be arranged randomly using a random number table, and individuals will be assigned to two groups according to A and B. This process is repeated until the sample volume is complete.
Blinding (investigator's opinion)	Double blinded
Blinding description	Outcome evaluators and expert statistics are not aware of the type of intervention and grouping
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

Floor 3; Bldg Emam Mosaa Kazem; University of Medical Sciences Complex; Sq Basij; Sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-12-01, 1398/09/10

Ethics committee reference number

IR.ARAKMU.REC.1398.249

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

sleep

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

3

Description of health condition studied

pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Level of anxiety

Timepoint

Measurement of the anxiety level at the night before surgery, one hour before the surgery

Method of measurement

State-Trait Anxiety Inventory (STAI)

2

Description

sleep quality

Timepoint

The morning of surgery

Method of measurement

St. Mary's Hospital Sleep Questionnaire

3

Description

Postoperative pain

Timepoint

Immediately after the patient's consciousness after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The researcher visits patients the night before surgery and completes a demographic questionnaire. Patients' anxiety will be measured using the Spielberger questionnaire. The researcher will practically teach the diaphragmatic breathing and ensure that the breathing is learned by the patient doing it correctly. Research units are required to perform this breathing exercise an hour before bedtime.

Diaphragmatic breathing One hour before bedtime, a researcher in the test group will be reminded of the diaphragmatic respiratory test unit's presence in the hospital. At 7am after patients wake up, sleep quality of last night will be measured by St. Mary's Hospital Sleep Questionnaire. One hour before transferring the research units to the operating room, they will be asked to breathe in the diaphragm. Then, before entering the operating room, patients' anxiety levels will be measured by the Spielberger questionnaire. Postoperative pain will be measured immediately after the patient's full consciousness after surgery using visual analogue scale.

Category

Treatment - Other

2

Description

Control group: The researcher will meet patients at the beginning of the night shift and complete a demographic questionnaire and patients' anxiety will be measured using the Spielberger questionnaire. At 7 o'clock in the morning after the patients wake up, the quality of their sleep last night will be measured by the St. Marie Questionnaire. Then, immediately before entering the

operating room, the anxiety level will be measured by the Spielberger questionnaire. Postoperative pain will be measured immediately after the patient's complete consciousness after surgery using a visual scale.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Vali-asr

Full name of responsible person

Yasaman Pourandish

Street address

Vali-asr Str, Vali-asr Hospital

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

pr_valieasr@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Floor 3; Bldg Emam Mosaa Kazem; University of Medical Sciences Complex; Sq Basij; Sardasht

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Email

research@arakmu.ac.ir

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

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

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3505

Email

hekmatpou@yahoo.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Yasaman Pourandish

Position

MSc Student of Medical Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street addressSchool of Nursing; University Complex Payambar
Azam; Sq Basij; Sardasht.**City**

Arak

Province

Markazi

Postal code

3831667493

Phone

+98 86 3417 3507

Email

y.pourandish@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Yasaman Pourandish

Position

MSc Student of Medical Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street addressSchool of Nursing; University Complex Payambar
Azam; Sq Basij; Sardasht.**City**

Arak

Province

Markazi

Postal code

3831667493

Phone

+98 86 3417 3507

Email

y.pourandish@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpou

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street addressSchool of Nursing ; University Complex Payambar
Azam; Sq Basij; Sardasht.**City**

Arak

Sharing plan**Deidentified Individual Participant Data Set (IPD)**Undecided - It is not yet known if there will be a plan to
make this available**Study Protocol**Undecided - It is not yet known if there will be a plan to
make this available**Statistical Analysis Plan**

Not applicable

Informed Consent FormUndecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable