Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of diaphragmatic and pursed lip breathing on the anxiety of patients undergoing hysterectomy surgery

Protocol summary

Study aim
Comparison of diaphragmatic breathing and bulb lining on the anxiety level of patients under hysterectomy

Design
In this study, 126 patients who are referred to Taleghani hospital in Arak and are candidate for hysterectomy are selected. Participants are divided into two intervention groups and a control group using random numbers table and blocking technique. To hide groups from participants, collectors and data analyzers, one code is assigned to each group.

Settings and conduct
This study will be conducted at Taleghani Hospital in Arak.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The presence of benign and malignant gynecological problems; Being alert after surgery; being hospitalized at least one day before and two days after the surgery. Exit criteria: Having another surgery in addition to ovariectomy; Having a history of using breathtaking techniques to control anxiety; Haveing a history of taking sedative, analgesic for more than a month; Need intensive care unit after surgery;Having diseases like psychological disorders, sensory and motor disorders, visual impairment and hearing loss; Having drug addiction.

Intervention groups
First, the diaphragm breathing technique (DB) is taught to group A and the Pursed Lip Breathing technique (PLB) is taught to group B using simple and intelligible sentences, by face to face individual training. Individuals in the control group do not receive any intervention from the researcher. Only the researcher will be present at his bed for 20 minutes without giving the patient any education and will fill in the demographic questionnaire and the Spielberger Anxiety Measurement scale. This will be done to reduce the impact of the educator's presence effect on reducing anxiety.

Main outcome variables
Anxiety level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180103038211N4**
Registration date: **2018-06-05, 1397/03/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-05, 1397/03/15**
Update count: **0**

Registration date
2018-06-05, 1397/03/15

Registrant information

Name
Fahime Davodabady

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3226 7610

Email address
F_davodabady@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01

Expected recruitment end date
2018-07-11, 1397/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of diaphragmatic and pursed lip breathing on the anxiety of patients undergoing hysterectomy surgery

Public title
The effect of diaphragmatic pursed lip breathing on the anxiety of hysterectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The presence of benign and malignant gynecological problems Being alert after surgery being hospitalized at least one day before and two days after the surgery Patient Satisfaction to Participate in Research
Exclusion criteria:
Having another surgery in addition to ovariectomy Having a history of using breathtaking techniques to control anxiety Haveing a history of taking sedative, analgesic or antianxiety drugs for more than a month Incidence of surgical complications such as severe bleeding, acute infection and hospitalization in intensive care unit Having diseases like psychological disorders, sensory and motor disorders, visual impairment and hearing loss Having drug addiction

Age
From **20 years** old to **59 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization was used. Random numbers table was used to determine the blocks.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Individuals in one group are unaware of the type of intervention in other groups. Also, the person who collects data for each group is unaware of the intervention of other groups. The data analyzer will be unaware of the type of intervention assigned to each group.

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 Square, Sardasht
City
Arak
Province
Markazi
Postal code
6941-7-38481

Approval date
2017-11-22, 1396/09/01

Ethics committee reference number
IR.ARAKMU.REC.1396.168

Health conditions studied

1

Description of health condition studied
ANEXITY

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Level of anxiety

Timepoint
Measurement of the anxiety level at the night before surgery, half an hour before the surgery, and after full vigilance after surgery

Method of measurement
Spielberg-er Questionnaire, State-Trait Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: First, diaphragmatic breathing (DB) is taught to patients using simple and intelligible sentences through individualized face to face training .In order to ensure that the type of respiration is taught in

the correct way in each group, trained patients will perform the trained breathing in the presence of the researcher in two 20-minute sessions with a two hour interval just a day before the surgery.Diaphragmatic breathing technique is as follows: Patient lies in a comfortable position on the back. Then, puts one hand on the chest and the other hand on the abdomen. In this position, patient exhales somehow, the hand on the abdomen to be pulled forward while pushing in and brings out the air from lungs slowly. During the expiration, holds the hand on the chest in the same condition.

Category

Treatment - Other

2

Description

Intervention group 2: First, pursed lip breathing (PLB) is taught to patients using simple and intelligible sentences through individual face to face training .In order to ensure that the type of respiration is taught in the correct way in each group, trained patients will perform the trained breathing in the presence of the researcher in two 20-minute sessions with a two hour interval just a day before the surgery. Breathing technique: The patient sits in a comfortable position and closes his/her mouth and breathes a deep breath through the nose and with the lips of the bud (whistling mode) exhales air through the mouth. The patient should breathe so that expiration time (exhale through the mouth) will be twice of the inspiration time (inhale air through the nose). That means inspiration time will be 2 seconds and expiration time will be 4 seconds.

Category

Treatment - Other

3

Description

Control group: Individuals in the control group do not receive any intervention. Only the researcher will be present at the bedside for 20 minutes without giving the education to the patient and will fill in the demographic questionnaire and the Spielberger anxiety test. This action will be done to remove the effect of the researcher's presence.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Fahimeh Davodabady

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Phone

+98 86 3417 3503

Email

fahimedavodabady@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Phone

+98 86 3417 3503

Email

arjomandzadegan@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

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fahimeh Davodabady

Position

1- Instructor

Latest degree

Master
Other areas of specialty/work
Nursery
Street address
Arak University of Medical Sciences, Basij Square, Sardasht
City
Arak
Province
Markazi
Postal code
6941-7-38481
Phone
+98 86 3417 3503
Email
fahimedavodabady@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Fahimeh Davodabady
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Arak University of Medical Sciences, Basij Square, Sardasht
City
Arak
Province
Markazi
Postal code
6941-7-38481
Phone
+98 86 3417 3503
Email
fahimedavodabady@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Fahimeh Davodabady
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Arak University of Medical Sciences, Basij Square, Sardasht
City
Arak
Province
Markazi
Postal code
6941-7-38481
Phone
+98 86 3417 3503
Email
fahimedavodabady@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available