# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## A nurse-led, Non-Pharmacological Interventions for Pain and Anxiety Reduction During Drain Tube Removal among Bariatric Patients: A Randomized Comparative Trial

## Protocol summary

**Study aim**

To identify the effect of cold gel packs, deep breathing exercises, a combination of cold gel packs and deep breathing exercises, and guided meditation on pain and anxiety during drain tube removal among post-bariatric surgery patients.

**Design**

The true experimental (comparative) design. Five study groups (A, B, C, D, and E) will be used in this study for two phases (before and after drain tube removal). For each, 40 patients will be collected by a simple randomization method at a single center.

**Settings and conduct**

The study will be performed at Al-Basrah Teaching Hospitals (Al-Sader, Al-Faiha, Al-Mawana, Al-Sayyab, and Al-Mawaddah Private Hospital). In a single-blinded design, the researcher will cover the cold gel packs with a single layer of medical-grade gauze, and also, they will be instructed to inhale deeply through their nose and exhale slowly through semi-closed lips.

**Participants/Inclusion and exclusion criteria**

Inclusion: ages between 18 and 65 years, any bariatric surgery, patients with a BMI > 40 kg/m² or a BMI > 35 kg/m² with comorbid diseases. Exclusion: patients with cancer, communication difficulties, heart failure, liver failure, kidney failure, drug addiction or alcoholism, psychological issues, and sleep disorders.

**Intervention groups**

The patients were divided into five groups: Group A, cold gel packs. Group B, deep breathing exercises. Group C, a combination of cold gel packs and deep breathing exercises. Group D, guided meditation. Group E, without any intervention.

**Main outcome variables**

main outcome will be change in the pain and anxiety levels during drain tube removal

## General information

**Reason for update**

**Acronym**

NIPAR-B

**IRCT registration information**

IRCT registration number: **IRCT20250306064953N2**
Registration date: **2025-06-02, 1404/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-02, 1404/03/12**
Update count: **0**

**Registration date**

2025-06-02, 1404/03/12

**Registrant information**

**Name**
Ali Tiryag
**Name of organization / entity**
University of Basrah
**Country**
Iraq
**Phone**
+964 781 173 5332
**Email address**
ali.malik@uobasrah.edu.iq

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-03-01, 1403/12/11

**Expected recruitment end date**

2025-07-01, 1404/04/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
A nurse-led, Non-Pharmacological Interventions for Pain and Anxiety Reduction During Drain Tube Removal among Bariatric Patients: A Randomized Comparative Trial

**Public title**
Comfort Without Medications: Nurse-Led Ways to Reduce Pain and Anxiety During Drain Removal After Bariatric Surgery

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Adults aged 18–60 years Underwent bariatric surgery (e.g., sleeve gastrectomy, gastric bypass) with postoperative surgical drain placement. Conscious, oriented, and able to communicate effectively in the language used for interventions and assessments. Drain tube scheduled for removal within 48–72 hours postoperatively. Willing to participate and provide written informed consent. Stable vital signs (as determined by the attending physician/nurse). Pain score ≥3 on a 0–10 numerical rating scale before the drain removal (to ensure intervention relevance).

**Exclusion criteria:**
Psychiatric or cognitive disorders that interfere with communication, comprehension, or cooperation (e.g., dementia, schizophrenia). Hearing or visual impairments that would hinder the ability to participate in guided meditation or deep breathing instructions. Use of sedatives, opioids, or anxiolytics within 4 hours prior to the drain removal. Postoperative complications (e.g., infection, bleeding, hemodynamic instability) that might require emergency care. Known allergy or intolerance to cold therapy or materials used in gel packs. History of chronic pain conditions or current use of long-term pain management therapy. Participation in another clinical trial that may interfere with this study.

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
To ensure the integrity of a randomization procedure that is both transparent and grounded in scientific principles, probability sampling (simple randomization) will be used in assigning patients to cold gel packs, deep breathing exercises, and control groups with the presumption that every patient has an equal probability of being placed in any particular group. During the randomization process, one letter will be selected from a sealed envelope containing three letters. On the back side of every card, the letters ‘A,’ ‘B,’ ‘C,’ ‘D,' or ‘E' will be written (A will be in the cold gel packs group, B will be in the deep breathing exercises group, C will be in the combination group, D in the meditation group, and E will be in the control group).

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
In this single-blind design, the researcher will preserve the gel packs in the freezer for at least 2 hours before covering them with a single layer of medical-grade gauze, and They will be instructed to inhale deeply through their nose and exhale slowly through semi-closed lips while keeping their eyes closed for 5 min.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Ethics committee of Baghdad college of nursing

**Street address**
Bab Al Muadham

**City**
Baghdad

**Postal code**
10047

**Approval date**
2025-05-06, 1404/02/16

**Ethics committee reference number**
50

## Health conditions studied

**1**

**Description of health condition studied**
Bariatric Surgery

**ICD-10 code**
L98.7

**ICD-10 code description**
Excessive and redundant skin and subcutaneous tissue

## Primary outcomes

**1**

**Description**
Reduction in self-reported pain and anxiety levels during

drain tube removal through nurse-led, non-pharmacological interventions in bariatric patients.

**Timepoint**

Twenty minutes Before intervention and immediately after intervention

**Method of measurement**

Patients will be asked to rate their pain by using the Visual Analogue Scale (0-10) before and immediately after drain tube removal. A lower number (0) indicates no pain; (1-3) indicates mild pain, (4-6) moderate pain, (7-9) severe pain, and (10) indicates the worst pain. Also, anxiety levels will be measured by using a six-item state anxiety scale derived from the State-Trait Anxiety Inventory, which consists of six items only, each item [1: No at all, 2: Somewhat, 3: Moderate So, 4: Very much so] before and immediately after drain tube removal.

## Secondary outcomes

### 1

**Description**

1. Physiological responses during drain removal.

**Timepoint**

Changes in heart rate, blood pressure, and respiratory rate will be measured before and after the procedure to objectively assess stress and anxiety levels.

**Method of measurement**

sphygmomanometer for blood pressure measurement and pulse oximetry for oxygen saturation

### 2

**Description**

2. Patient satisfaction with care.

**Timepoint**

before and after intervention

**Method of measurement**

Assessed using a validated satisfaction scale or Likert-type questionnaire to evaluate patients' perceptions of the nurse-led interventions.

### 3

**Description**

3. Procedure duration.

**Timepoint**

before and after intervention

**Method of measurement**

Time taken to complete the drain removal, recorded in minutes, to determine whether the interventions affect procedural efficiency.

## Intervention groups

### 1

**Description**

Intervention group: Cold Gel Packs. The cold application technique involves the removal of a drain tube with the use of a cooling gel pack. The researcher will preserve the gel packs in the freezer for at least 2 hours before covering them with a single layer of medical-grade gauze. The packs will then be applied to the area surrounding the drain tube for 10–20 minutes before their withdrawal. This technique has been proven effective in reducing discomfort and pain during the removal process.

**Category**

Other

### 2

**Description**

Intervention group: Deep Breathing Exercises. Another technique is the deep breathing exercise technique. They will be instructed to inhale deeply through their nose and exhale slowly through semi-closed lips while keeping their eyes closed for 5 min. Participants will be asked to perform breathing exercises before removing the drain tube. This technique has been shown to reduce anxiety and promote relaxation during the procedure.

**Category**

Other

### 3

**Description**

Intervention group: Combination of cold gel packs and deep breathing exercises. The researcher will preserve the gel packs in the freezer for at least 2 hours before covering them with a single layer of medical-grade gauze. The packs will then be applied to the area surrounding the drain tube for 10–20 minutes before their withdrawal. They will be instructed to inhale deeply through their nose and exhale slowly through semi-closed lips while keeping their eyes closed for 5 min. Participants will be asked to perform breathing exercises before removing the drain tube.

**Category**

Other

### 4

**Description**

Intervention group: Guided meditation. Guided imagery therapy can incorporate the use of relaxation techniques, such as diaphragmatic breathing and a musical background, to help the participant focus and stay focused. The therapy session started with soft background music with nature sounds (sea and seagulls) and audio that invited the participant to stand in a comfortable position on the bed with their eyes closed and then perform movements of slow and expansive breathing and relaxation in various parts of the body.

**Category**

Other

### 5

**Description**

Control group: The drain tube removal will be performed without any intervention. Participants in the control group will receive routine standard care during drain tube removal, without any additional non-

pharmacological interventions. This includes general reassurance and standard nursing practices typically performed during the procedure, such as verbal communication and basic comfort measures, but excludes specific interventions like cold gel packs, guided breathing, or meditation.

**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Al-Basrah Teaching Hospital
**Full name of responsible person**
Ali Malik Tiryag
**Street address**
Basrah Center, Al-Saadi Street
**City**
Basrah
**Postal code**
61004
**Phone**
+964 781 173 5332
**Email**
ali.malik@uobasrah.edu.iq
**Web page address**
https://basrah-health.gov.iq

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
College of Nursing/University of Baghdad
**Full name of responsible person**
Ali Malik Tiryag
**Street address**
Bab Al Muadham
**City**
Baghdad
**Postal code**
10047
**Phone**
+964 781 173 5332
**Email**
ali.malik@uobasrah.edu.iq
**Web page address**
http://conursing.uobaghdad.edu.iq/

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
The author of the trial is the funding source
**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**
Other

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
College of Nursing/University of Baghdad
**Full name of responsible person**
Ali Malik Tiryag
**Position**
PhD Student/Lecturer
**Latest degree**
Master
**Other areas of specialty/work**
Nursing
**Street address**
Basrah Center, Bab Al-Zubair Campus
**City**
Basrah
**Province**
Basrah
**Postal code**
61004
**Phone**
+964 781 173 5332
**Email**
ali.malik@uobasrah.edu.iq
**Web page address**
https://faculty.uobasrah.edu.iq/faculty/3300

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
College of Nursing/University of Baghdad
**Full name of responsible person**
Ali Malik Tiryag
**Position**
PhD Student/Lecturer
**Latest degree**
Master
**Other areas of specialty/work**
Nursing
**Street address**
Basrah Center, Bab Al-Zubair Campus
**City**
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**Province**
Basrah
**Postal code**
61004
**Phone**
+964 781 173 5332
**Email**

ali.malik@uobasrah.edu.iq

**Web page address**

https://faculty.uobasrah.edu.iq/faculty/3300

## Person responsible for updating data

**Contact**

**Name of organization / entity**

College of Nursing/University of Baghdad

**Full name of responsible person**

Ali Malik Tiryag

**Position**

PhD Student/Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Nursing

**Street address**

Basrah Center, Bab Al-Zubair Campus

**City**

Basrah

**Province**

Basrah

**Postal code**

61004

**Phone**

+964 781 173 5332

**Email**

ali.malik@uobasrah.edu.iq

**Web page address**

https://faculty.uobasrah.edu.iq/faculty/3300

## 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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

The data will be the results of a six-item state anxiety scale derived from the State-Trait Anxiety Inventory that measures patients' anxiety levels and a numerical pain scale to measure pain levels in both control and intervention groups.

**When the data will become available and for how long**

God willing, once the process of data collection, analysis, and successfully publishing the manuscript is finished, all the related files will become available for 6 months after publication.

**To whom data/document is available**

With academic nurses and any researcher who is interested in the data.

**Under which criteria data/document could be used**

The data could be used after getting the permission via email. Also, users need to acknowledge the owner

**From where data/document is obtainable**

Users can ask for the data and the permission via email. Ali Malik Tiryag is the corresponding author. He will be in contact with whoever asks for the data. His email is ali.malik@uobasrah.edu.iq

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

Users can ask for the data and the permission via email. Ali Malik Tiryag is the corresponding author. He will be in contact with whoever asks for the data. His email is ali.malik@uobasrah.edu.iq

**Comments**

Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfill their academic endeavors.