

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Benson and Jacobsen relaxation techniques on anxiety in inguinal hernia patients under spinal anesthesia

#### Protocol summary

relaxation technique, vital signs

#### Study aim

Determining the effect of Benson and Jacobsen relaxation techniques on the anxiety level of inguinal hernia patients under spinal anesthesia in the operating room of Hakim Neishabour Hospital.

#### Design

This interventional study has a control group, with parallel groups in a double-blind randomized manner.

#### Settings and conduct

The place of study is the operating room of Hakim Neishabur Hospital. Measuring anxiety in people using the Spielberger State Anxiety Questionnaire will be done in two time periods before the intervention and after the intervention (immediately before the spinal technique). Also, the patients' vital signs will be measured in these two intervals.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: • A person's ability to communicate • Not suffering from psychological disorders • No history of taking anti-anxiety drugs • Elective and non-emergency inguinal hernia surgery • No history of drug use • Age over 18 years • Performing spinal anesthesia for the first time  
Exclusion criteria: • Unwillingness to continue cooperation in the study • Aggravation of the patient's physical condition • History of spinal anesthesia

#### Intervention groups

The way of doing work in Jacobsen's intervention group is as follows: This will be done 30 minutes before anesthesia. In the Benson relaxation group, the following steps will be performed: This will be done 30 minutes before spinal anesthesia. For the control group, sedation interventions will not be performed and only the usual nursing training will be provided to them like the intervention group. Of course, at the end of the study, the study results and educational pamphlets will be provided to this group as well.

#### Main outcome variables

Anxiety, Benson relaxation technique, Jacobson

#### General information

##### Reason for update

##### Acronym

تکنیک های آرام سازی

##### IRCT registration information

IRCT registration number: **IRCT20230721058870N1**

Registration date: **2023-09-22, 1402/06/31**

Registration timing: **prospective**

Last update: **2023-09-22, 1402/06/31**

Update count: **0**

##### Registration date

2023-09-22, 1402/06/31

##### Registrant information

##### Name

mehrdad rohaninasab

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3609 3931

##### Email address

mehrdad\_mashhad74@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The effect of Benson and Jacobsen relaxation techniques on anxiety in inguinal hernia patients under spinal anesthesia

## Public title

The effect of Benson and Jacobsen relaxation techniques on anxiety in inguinal hernia patients under spinal anesthesia

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

• A person's ability to communicate • Not suffering from psychological disorders • No history of taking anti-anxiety drugs • Elective and non-emergency inguinal hernia surgery • No history of drug use • Age over 18 years • Performing spinal anesthesia for the first time

### Exclusion criteria:

Unwillingness to continue cooperation in the study  
Aggravation of the patient's physical condition  
Reluctance to use spinal anesthesia  
Failure to perform spinal Intraoperative change from spinal to general anesthesia

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **105**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The samples of this research will be selected in an accessible and purpose-based manner at first, and then a random allocation list will be generated using the block randomization method with blocks of 3, by the Random Allocation software, based on which these 105 people will be randomly selected. Benson relaxation technique, Jacobsen relaxation technique and control group (35 people in each group) will be placed in 3 groups. The order of assigning people to groups will be based on the list.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The random assignment of people in groups will be done by someone who does not know about the division of people into groups. Also, patients are unaware of the existence of other study groups. The statistical analyst will also be unaware of the allocation of people in groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Neyshabur University of Medical Sciences

##### Street address

Neyshabur University of Medical Sciences

##### City

Neyshabur

##### Province

Razavi Khorasan

##### Postal code

9319774448

#### Approval date

2023-07-04, 1402/04/13

#### Ethics committee reference number

IR.NUMS.REC.1402.007

## 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

Inguinal hernia

#### ICD-10 code

K40

#### ICD-10 code description

Inguinal hernia

## Primary outcomes

### 1

#### Description

anxiety

#### Timepoint

Measuring anxiety in people using the Spielberger State Anxiety Questionnaire will be done in two time periods before the intervention and after the intervention (immediately before the spinal technique). Also, the patients' vital signs will be measured in these two intervals.

## Method of measurement

Spielberger anxiety questionnaire and tools for measuring vital signs including a calibrated monitoring system in the operating room

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: jacobsen relaxation technique

#### Category

N/A

### 2

#### Description

Intervention group: benson relaxation technique

#### Category

N/A

### 3

#### Description

Control group: Without the intervention of relaxation techniques

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Neishabur Hakim Hospital

##### Full name of responsible person

Mehrdad Rohaninasab

##### Street address

Neishabur Hakim Hospital

##### City

Neyshabur

##### Province

Razavi Khorasan

##### Postal code

9319774448

##### Phone

+98 51 4262 3415

##### Email

mehrdad\_mashhad74@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Neyshabour University of Medical Sciences

## Full name of responsible person

Dr. Mostafa Arabi

## Street address

Neyshabur University of Medical Sciences

## City

Neyshabur

## Province

Razavi Khorasan

## Postal code

9319774448

## Phone

+98 51 4330 6204

## Email

marabi@nums.ac.ir

## Grant name

## Grant code / Reference number

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

Yes

## Title of funding source

Neyshabour 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

Neyshabour University of Medical Sciences

#### Full name of responsible person

Mehrdad Rohaninasab

#### Position

Faculty member

#### Latest degree

Master

#### Other areas of specialty/work

Nursery

#### Street address

Neyshabur University of Medical Sciences

#### City

Neyshabur

#### Province

Razavi Khorasan

#### Postal code

9188687975

#### Phone

+98 51 3609 3931

#### Email

mehrdad\_mashhad74@yahoo.com

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Neyshabour University of Medical Sciences

**Full name of responsible person**

Mehrdad Rohaninasab

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Neyshabur University of Medical Sciences

**City**

Neyshabur

**Province**

Razavi Khorasan

**Postal code**

9188687975

**Phone**

+98 51 3609 3931

**Email**

mehrdad\_mashhad74@yahoo.com

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Neyshabour University of Medical Sciences

**Full name of responsible person**

Mehrdad Rohaninasab

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Neyshabr University of Medical Sciences

**City**

Neyshabur

**Province**

Razavi Khorasan

**Postal code**

9188687975

**Phone**

+98 51 3609 3931

**Email**

mehrdad\_mashhad74@yahoo.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**

After collecting the data

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

After printing the article

**To whom data/document is available**

Academic researchers and community members

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

By mentioning the names of the authors of the present study

**From where data/document is obtainable**

neyshabur university of medical sciences mehrdad

rohaninasab 09156295519

mehrdad\_mashhad74@yahoo.com

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

Calling the author's phone or email or visiting Neishabur University of Medical Sciences in person

**Comments**