

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study on the effect of benson and progressive muscle relaxation techniques on the severity of pain after laminectomy

#### Protocol summary

##### Study aim

the aim of this study was to compare the effects of Benson and progressive muscle relaxation on the severity of pain after laminectomy surgery

##### Design

93 patients were randomly divided into three intervention groups including Benson relaxation, progressive muscle relaxation and control. Random assignment was performed by use of dice numbers. Patients in all groups received routine treatment (analgesic medications) in addition to corresponding interventions.

##### Settings and conduct

This study was performed on patients undergoing lumbar laminectomy in selected AJA hospital in Tehran. Relaxation techniques were done at three stages after laminectomy (2, 12 and 24 hours after recovery). Severity of pain was assessed before and 20 minutes after each relaxation period using visual analogue scale (VAS).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age range of 18-65 years, ability of learning, being interested to do relaxation techniques and having permission from own physician. Exclusion criteria: psychological disorders, cognitive impairments, addiction to opioids, those who used sleeping pills and muscle relaxant drugs.

##### Intervention groups

Intervention group 1 (Benson relaxation): Patients in this group performed Benson relaxation technique. This procedure including lie down, closing the eyes, relaxing the muscles from the bottom up, starting to breathe slowly, continuing to breathe slowly as the muscles relax, open Eyes slowly and away from negative thoughts. Intervention group 2 (progressive muscle relaxation): Patients in this group performed progressive muscle relaxation technique. In this method, the individual relaxes each of his muscles (from the leg muscles to the facial muscles) by counting to 5 contractions and then counting to 10. group 3 (control group): In this group no

relaxation techniques were performed on the patients.

##### Main outcome variables

pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161213031385N3**

Registration date: **2020-01-10, 1398/10/20**

Registration timing: **retrospective**

Last update: **2020-01-10, 1398/10/20**

Update count: **0**

##### Registration date

2020-01-10, 1398/10/20

##### Registrant information

##### Name

Seyed Amir Hosein Pishgooie

##### Name of organization / entity

Army university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7750 0201

##### Email address

ah.pishgooie@ajaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-09-23, 1395/07/02

##### Expected recruitment end date

2016-12-20, 1395/09/30

##### Actual recruitment start date

2016-09-23, 1395/07/02

**Actual recruitment end date**

2016-12-20, 1395/09/30

**Trial completion date**

2016-12-21, 1395/10/01

**Scientific title**

Comparative study on the effect of benson and progressive muscle relaxation techniques on the severity of pain after laminectomy

**Public title**

The effect of relaxation techniques on pain

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

ability of learning having reading and writing skills being interested to do relaxation techniques having permission from own physician

**Exclusion criteria:**

psychological disorders hearing and motor disorders addiction to opioids those who used sleeping pills and muscle relaxant drugs

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **93**

Actual sample size reached: **93**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were selected by a consecutive sampling method and randomly assigned to three groups of Benson relaxation (n=31), progressive muscle relaxation (n=31), and control (n=31). Dice were used to randomly assign individuals to groups. Dice number 1 and 2 were assigned for Benson relaxation group, 3 and 4 for progressive muscle relaxation and 5 and 6 for control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of aja university of medical sciences

**Street address**

aja university of medical sciences, Etemadzade st, Fatemi st

**City**

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**Province**

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**Postal code**

1411718541

**Approval date**

2016-08-21, 1395/05/31

**Ethics committee reference number**

IR.AJAUMS.REC.1395.13

**Health conditions studied****1****Description of health condition studied**

Pain after Laminectomy

**ICD-10 code**

G89.1

**ICD-10 code description**

Acute pain, not elsewhere classified

**Primary outcomes****1****Description**

Patients' pain score based on VAS scale

**Timepoint**

Before surgery, 2, 12 and 24 hours after consciousness

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group 1: Benson relaxation group \_ In this group, patients performed the Benson relaxation technique, which is a passive relaxation technique. This relaxation procedure is done in six steps, including lie down, closing the eyes, relaxing the muscles from the bottom up (without active contraction), starting to breathe slowly, continuing to breathe slowly as the muscles relax, open Eyes slowly and away from negative thoughts. This technique was performed three times after laminectomy (2, 12 and 24 hours after consciousness). Pain intensity was measured before and 20 minutes after each relaxation by visual analogue

scale (VAS).

**Category**

Behavior

**2**

**Description**

Intervention group 2: Progressive muscle relaxation group \_ Patients in this group performed progressive muscle relaxation techniques, which are active relaxation techniques. In this method, the individual relaxes each of his muscles (from the leg muscles to the facial muscles) by counting to 5 contractions and then counting to 10. These steps are respectively for the leg muscles, femurs, abdomen, chest, buttocks, hands and forearm, arms, shoulders, neck, forehead, tongue and jaw, eyes and face until the patient feels his whole body loosely integrated, Has been repeated. This technique was performed three times after laminectomy (2, 12 and 24 hours after consciousness). Pain intensity was measured before and 20 minutes after each relaxation by visual analogue scale (VAS).

**Category**

Behavior

**3**

**Description**

Control group: Individuals in the control group received only routine treatment and they were not given any training or relaxation technique

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam reza hospital

**Full name of responsible person**

Reza Momen

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Emam Reza Hospital, Etemadzade st, Fatemi st, Tehran

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Armin Zareian

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AJA University of Medical Sciences, Etemadzade st, Fatemi st, Tehran

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Artesh 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**

Artesh University of Medical Sciences

**Full name of responsible person**

Reza Momen

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**

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**

Yes - There is 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

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

Pain score and demographic information

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

3 months after the completion of the study

**To whom data/document is available**

Researchers in Medical Sciences

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

unlimited

**From where data/document is obtainable**

Send email to rezamomen88@yahoo.com

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

The request will be sent within three weeks

**Comments**