

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect of Benson relaxation technique on the severity of pain caused by spinal anesthesia after general and urological surgery in the candidates of elective and general surgeries

#### Protocol summary

##### Study aim

The aim of this study was to investigate the effect of Benson's relaxation on the severity of pain caused by spinal anesthesia during surgery.

##### Design

In this study, 60 patients who are candidates for Urology and general surgery and will be anesthetized in the spinal method, will be randomly selected and assigned into two intervention and control groups. For randomization, the same cards which characterized by 1 and 2 will be used.

##### Settings and conduct

This study will be done in general surgery and Urology wards of Imam Reza hospital in Kermanshah. The intervention group will be trained using audio files and educational brochures before surgery. On the surgery day, after the start of pain in the anesthetized area, the pain level will be evaluated using the VAS questionnaire, and then Benson relaxation will be performed for 10-20 minutes, and the pain will be assessed again by the VAS questionnaire.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients at the age of 18-60 years old; Having reading and writing skills; existing pain in the anesthetized area; Written consent. Exclusion criteria: Having mental or nervous disorders; Using sedative medications; Drug addiction; Mental and motor disorders.

##### Intervention groups

The intervention group will receive Benson relaxation for 10-20 minutes after the start of pain in the anesthetized area on the day of surgery. Control group will not receive any intervention and they will receive routine treatment.

##### Main outcome variables

pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130603013568N6**

Registration date: **2018-06-22, 1397/04/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-22, 1397/04/01**

Update count: **0**

##### Registration date

2018-06-22, 1397/04/01

##### Registrant information

##### Name

Rostam Jalali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3724 6613

##### Email address

rjalali@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-22, 1397/04/01

##### Expected recruitment end date

2018-08-23, 1397/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of Benson relaxation technique on the severity of pain caused by spinal anesthesia after general and urological surgery in the candidates of elective and general surgeries

## Public title

The effect of Benson's relaxation technique on spinal anesthesia pain

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients at the age of 18-60 years old Having reading and writing skills Pain in the anesthetized area Written consent

### Exclusion criteria:

Psychiatric and neurologic disorder Use of sedative medications Drug addiction Mental and motor disorders

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization will be done using random number table.

## 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 Kermanshah University of Medical Sciences

##### Street address

Shahid Beheshti Blvd

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

## Approval date

2018-05-22, 1397/03/01

## Ethics committee reference number

IR.KUMS.REC.1397.126

## Health conditions studied

### 1

#### Description of health condition studied

Pain

#### ICD-10 code

G89.18

#### ICD-10 code description

Other acute postprocedural pain

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before and after intervention

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the intervention group, on the day of surgery after the patient arrives at the ward, the ending time of anesthetizing is evaluated by the investigator. This assessment involves checking the return of the sense of hands and feet using the needle and checking the abdominal and leg muscle tone. After the start of pain in anesthetized area, it is assessed using the pain intensity scale. After evaluation, the patient will benefit from the usual palliative care, at this time the relaxation method will be used in this way: The patient is asked to be in a comfortable position, Closing his eyes slowly and relaxing all the muscles deeply beginning from the legs and go ahead on the face and keeps this relaxed state. At the same time the patient should breath via nose and should be aware of or pay attention to his/her breathing. After that he/she should breath out via mouth whispering the word "one" and breathing as usual. This process will be repeated every 10 to 20 minutes based on patient tolerance.

#### Category

Treatment - Other

### 2

#### Description

The control group will not receive any intervention but

will receive the routine treatment.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Reza hospital

**Full name of responsible person**

Zahra Keihani

**Street address**

No.10, Mahdieh Ave

**City**

Ghorveh

**Province**

Kurdistan

**Postal code**

6661847499

**Phone**

+98 87 3522 4171

**Email**

ZPK60@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farid Najafi

**Street address**

Vice chancellor for Research and Technology, No 2 Building, Shahid Beheshti Blvd.

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3835 8259

**Email**

daftarriasat@Kums.ac.ir

**Web page address**

<http://www.Kums.ac.ir>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Rostam Jalali

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Nursing Department ,Faculty of Nursing and Midwifery, Dolat Abad Blvd

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Kermanshah

**Province**

Kermanshah

**Postal code**

6719851351

**Phone**

+98 83 3724 6613

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+98 83 3826 3048

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ks\_jalali@yahoo.com

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

Kermanshah University of Medical Sciences

**Full name of responsible person**

Rostam Jalali

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**Email**

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**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**

For keeping anonymous

**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