

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of Benson's relaxation technique on postoperative pain after total knee replacement in elder patients

Protocol summary

Summary

Pain score evaluation after knee arthroplasty ,before and after relaxation in both group patients, pain score before and after relaxation in the treatment group, pain score before and after examination in the control group, pain score after knee arthroplasty in regard to age and gender in control and treatment groups and blood pressure and analgesic administration before and after intervention in both groups were determined and compared. This randomized clinical trials with control group performed on seniors who's admitted to Shahid Beheshti and Millad hospitals in Kashan-Iran. Inclusion criteria for patients include: above 60 years old and use of spinal anesthesia for surgery. Exclusion criteria include: history of Benson relaxation technique, identified cognitive and mental problems, drug or alcohol abuse and severe visual and auditory disorders. The sample size is 34. 4h after surgery, visual instrument is used for evaluation of pain in both groups. In treatment group, relaxation will be performed on the first, second and third days after surgery (2 sessions in a day, each session 10-20 min with 6-8h interval between sessions). Pain evaluation in the treatment group is perform 30 min after intervention. Pain intensity, blood pressure and amount of prescribed analgesic drugs are evaluated in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053134279N1**

Registration date: **2017-11-12, 1396/08/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-12, 1396/08/21

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Shahid Sadoughi Faculty of Nursing and Midwifery, Yazd-Iran.

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Benson's relaxation technique on postoperative pain after total knee replacement in elder patients

Public title

The effect of Benson's relaxation technique on postoperative pain after total knee replacement in elder hospitalized patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for study: inclination to participate in research, at least 60 years old, patient's candidate for knee arthroplasty surgery, use of spinal anesthesia for surgery. Exclusion criteria for study: history of the Benson relaxation technique, identified cognitive and mental problems, drug or alcohol abuse and severe visual and auditory disorders. Sample loss criteria: refusal to continue to participate in research by patients, surgery complication like bleeding and infection, use of pain pump for pain control after knee arthroplasty.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Shahid Sadoughi University of Yazd

Street address

Alley Bu Ali, Street General Fallahi, Safaieh, Yazd

City

Yazd

Postal code

Approval date

2017-07-18, 1396/04/27

Ethics committee reference number

IR.SSU.REC.1396.81

Health conditions studied

1

Description of health condition studied

Total knee replacement

ICD-10 code

M23.4

ICD-10 code description

Loose body in knee

Primary outcomes

1

Description

Postoperative pain after total knee replacement

Timepoint

Relaxation method will be performing on treatment group patients in 1, 2 and 3 days after surgery. In each day tow 10-20 min sessions will be designed with 9-8h interval between sessions. Pain evaluation in treatment group will be performed 30 min after relaxation implantation.

Method of measurement

visual analog scale (VAS)

Secondary outcomes

1

Description

Blood pressure, narcotic drugs

Timepoint

blood pressure and amount of prescribed analgesic drugs are evaluated in both groups in 6 period after surgery.

Method of measurement

Barometer device, Patient records

Intervention groups

1

Description

Intervention group: Four hours after surgery, VAS method will be used for pain evaluation in control and treatment patients. Relaxation method will be performing on treatment group patients in 1, 2 and 3 days after surgery. In each day tow 10-20 min sessions will be designed with 6-8h interval between sessions. Pain evaluation in treatment group will be performed 30 min after relaxation implantation. Pain intensity, blood pressure and amount of prescribed analgesic drugs are evaluated in both groups in 6 period after surgery.

Category

Behavior

2

Description

Control group: Four hours after surgery with spinal anesthesia, VAS method used for pain evaluation in patients and pain intensity, blood pressure and amount of prescribed analgesic drugs are evaluated in both groups in 6 period after surgery.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti And Milad Kashan

Full name of responsible person

Marzieh Modarresi

Street address

Spring bombed 11, 6 meters of spring, maghmal Harir alley, Amir Kabir Street, Kashan

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Yazd University of Medical Sciences
city of Medical Sciences

Full name of responsible person

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Safaieh Street General Fallahi Alley Bu Ali

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Geriatric Nursing Master

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

Yes

Title of funding source

Vice chancellor for research, Yazd University of Medical Sciences
city of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery Shahid Sadoughi Yazd

Full name of responsible person

Behnaz Enjezab

Position

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empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty