Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of rhythmic breathing with subjective imaging on pain intensity during spinal needle insertion in patients undergoing spinal anesthesia

Protocol summary

Study aim
Comparison of the effect of rhythmic breathing with subjective imaging on pain during spinal needle insertion in patients undergoing spinal anesthesia

Design
The present study is a three-group clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3on 120 patients. In this study, R software will be used for randomization.

Settings and conduct
This study will be performed in the operating room of Bu Ali Sina Hospital in Hamadan. Patients who are candidates for surgery and the use of spinal anesthesia will be selected for this study. The spinal anesthesia technique is performed by a skilled anesthesiologist and the measurement of pain is recorded by the researcher based on the patients' statements.

Participants/Inclusion and exclusion criteria
- Age between 18 and 75 - No anatomical abnormalities in the lumbar region - Do not use painkillers - Do not use opium

Intervention groups
Patients are randomly divided into three groups: control, rhythmic breathing and mental imagery.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210828052307N1**
Registration date: **2021-09-19, 1400/06/28**
Registration timing: **prospective**

Last update: **2021-09-19, 1400/06/28**
Update count: **0**

Registration date
2021-09-19, 1400/06/28

Registrant information

Name
Elham Shakibanezhad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3827 8899

Email address
elhamshakiba09@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of rhythmic breathing with subjective imaging on pain intensity during spinal needle insertion in patients undergoing spinal anesthesia

Public title
Comparison of the effect of rhythmic breathing with subjective imaging on pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to communicate verbally No specific disease No anatomical problems in the lumbar area and skin No neurological disorders, plagia and paresis in the area of the lower thoracic vertebrae

Exclusion criteria:

Need to try to insert the needle more than once Lack of patient cooperation during spinal needle insertion Use of other methods to reduce pain Use of sedatives and hypnotics

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly assigned to one of three groups in order of entry. In order to be randomized, sixth blocks (ABABCC-ACABBC-BAACCB-ACCBAB-CBCABA-AABBCC - CCBAAB-CABABC-BCABCA, etc.) will be prepared according to the number of participants and placed in envelopes. Then, when the patients enter the study, one of the envelopes is removed from the bag by one of the nurses who has no role in the study and is sampled without permutation.

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 Hamadan University of Medical Sciences

Street address

Hamadan, Shariati Crossroads, Ayatollah Kashani Blvd., Hamadan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۶۸۷

Approval date

2021-08-01, 1400/05/10

Ethics committee reference number

IR.UMSHA.REC.1400.351

Health conditions studied

1

Description of health condition studied

Pain when inserting a spinal needle

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain when inserting a spinal needle

Timepoint

Pain will be measured immediately after spinal anesthesia.

Method of measurement

using a Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

In first intervention group, patients are given training individually by the researcher on the morning of the operation and in the surgery ward. In the rhythmic breathing group, patients are asked to perform rhythmic breathing before inserting a spinal needle as follows: close their eyes and do a deep, long breath through the nose with three numbers, then breathe in the lungs. Hold and count to 3, and then exhale slowly through the mouth with 3 numbers.

Category

Other

2

Description

In second intervention group, patients are given training individually by the researcher on the morning of the operation and in the surgery ward. In the mental imaging group, after the patients are placed on the operating table just before and during the insertion of the spinal needle, a sea sound is played to the patient by a headphone and he is asked to visualize the images in his mind at the same time.

Category

Prevention

3

Description
Control group: The patient is placed on a surgical bed, spinal anesthesia is performed by an anesthesiologist, and one minute after the procedure and the patient's hemodynamic status is confirmed, the patient is ask to indicate the severity of pain when the needle was inserted. .

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Booali Hospital

Full name of responsible person
Dr. Mohammad Mohsen Yeganeh

Street address
Mahdieh Street - next to the People's Park

City
Hamedan

Province
Hamadan

Postal code
6717225708

Phone
+98 81 3838 1025

Fax
+98 81 3262 1515

Email
booali@ac.ir

Web page address
http://192.168.20.42/hospw

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Seyed Reza borzou

Street address
Hamedan - Shahid Fahmideh Street - in front of People's Park

City
Hamedan

Province
Hamadan

Postal code
۶۵۱۷۸۳۸۶۸۷

Phone
+98 81 3252 0184

Fax
+98 81 3252 0188

Email
Webda@umsha.ac.ir

Web page address
https://www.umsha.ac.ir/

Grant name
No

Grant code / Reference number

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

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Seyed Reza Borzou

Position
Associate Professor Hamadan University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nursing education

Street address
Hamedan - Shahid Fahmideh Street - in front of People's Park

City
Hamedan

Province
Hamadan

Postal code
۶۵۱۷۸۳۸۶۸۷

Phone
+98 81 3252 0182

Fax
+98 81 3252 0184

Email
borzou@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Seyed Reza borzou

Position

Associate Professor Hamadan University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursing education

Street address

Hamedan - Shahid Fahmideh Street - in front of People's Park

City

Hamedan

Province

Hamadan

Postal code

38698 65178

Phone

+98 81 3838 0545

Fax

+98 81 3838 0447

Email

borzou@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Seyed Reza borzou

Position

Associate Professor Hamadan University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursing Education

Street address

Hamedan - Shahid Fahmideh Street - in front of People's Park

City

Hamedan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0545

Fax

+98 81 3838 0447

Email

borzou@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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