

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of nursing visit on preoperative anxiety and vital sings in the lumbar disk herniation surgery candidate patients

Protocol summary

Summary

(1)Objectives: To determine the effect of nursing visits on the level of preoperative anxiety and vital signs in patients undergoing lumbar disk herniation (2) Design: A random single-blind clinical trial (patients) (3) conduction: The patients' medical records is evaluated a day before surgery and the eligible ones are selected. Anxiety and vital signs (systolic and diastolic blood pressure, pulse rate, respiratory rate and temperature of both groups) are recorded using the Spielberger Anxiety Questionnaire 19 to 20 hours before the surgery. Then, the nursing visit is conducted for the intervention group. Nursing visit includes a 30 to 50 minute-meeting of the patient which is performed by the nurse researcher and during which all the necessary information about lumbar disc herniation, causes of the disease, symptoms, treatments, preoperative preparation, the time and the way of transferring patients to the operating room, waiting time in the operating room, information about the surgery and anesthesia team, type of anesthesia, environment and equipment of the operating room, recovery room, measures taken in recovery, transference to the ward, post-operative care in the ward and the necessary verbal post-operative care after discharge are provided to the patient. Moreover, some explanations are given using audio-visual equipment such as tablet that contains photos and descriptions of the operating room environment, characteristics and the outcomes of surgery to the intervention group. (4) Participants and the major eligibility criteria: Patients scheduled for elective lumbar disc herniation referred to neurosurgical ward at Besat hospital in sanandaj city. Inclusion criteria: Patients undergoing lumbar disc herniation surgery, volunteers to participate in the study, elective surgery. Exclusion criteria: taking anxiety drugs which include: Alprazolam; Oxazepam; Chlordiazepoxide and Diazepam (From 24 hours before the intervention to the time of remeasurement of anxiety) and withdrawing of patients for any reason(5) Interventions: Nursing visit (6) Main

consequence variables: anxiety and vital signs

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051627927N1**

Registration date: **2016-09-09, 1395/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-09, 1395/06/19

Registrant information

Name

behrooz zarei

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3323 2115

Email address

behroozzareei62@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2016-06-20, 1395/03/31

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of nursing visit on preoperative anxiety and vital signs in the lumbar disk herniation surgery candidate patients

Public title

The Effect of nursing visit on preoperative anxiety and vital signs

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing lumbar disc herniation surgery; volunteered to participate in the study; having elective surgery; surgery performed under general anesthesia or spinal anesthesia; No history of diseases such as high blood pressure; vascular disease; thyroid disease; rheumatoid arthritis; trauma to the lower back; fever; Lack of sedative-hypnotic drugs; no history of mental neurological disorders; lack of previous experience of surgery and the age between 18 to 65. Exclusion criteria: taking anxiety medications including Alprazolam; Oxazepam; Chlordiazepoxide and Diazepam (from 24 hours before the intervention to the time of remeasurement of anxiety) and withdrawal of patients for any reason

AgeFrom **18 years** old to **65 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**Blinding (investigator's opinion)**

Single 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 Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences Pasdaran street, Sanandaj city Kurdistan province, Islamic Republic Of Iran

City

Sanandaj

Postal code

66135 - 756

Approval date

2016-08-13, 1395/05/23

Ethics committee reference number

IR.MUK.REC.1395/132

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

lumbar Herniation Disk

ICD-10 code

55.1

ICD-10 code description

Lumbar and other intervertebral disc disorders with radiculopathy

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

Anxiety

Timepoint

Before the intervention and the day after the intervention

Method of measurement

Spielberger Anxiety Questionnaire

2**Description**

Vital signs

Timepoint

Before the operation and the day after the operation

Method of measurement

Sphygmomanometer, Stethoscope, Tympanic Thermometers

Secondary outcomes

empty

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

Intervention group: 19 to 20 hours in the day prior to the surgery all the necessary information about lumbar disc herniation, causes of the disease, symptoms, treatments, preoperative preparation, the time and the way of transferring patients to the operating room, waiting time in the operating room, information about the surgery and

anesthesia team, type of anesthesia, environment and equipments of the operating room, recovery room, measures taken in recovery, transference to the ward, post-operative care in the ward and the necessary verbal post-operative care after discharge are provided to the patients in a 30 to 50 minute visit. Moreover, some explanations are given using audio-visual equipments such as tablet that contains photos and descriptions of the operating room, the characteristics and the results of the surgery to the intervention group.

Category

Prevention

2

Description

There is no intervention and receive routine care alone.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Behrooz Zarei, Bachelor of Nursing

Street address

Department of Neurosurgery, Besat Hospital,
Keshavarz street, Sanandaj city

City

sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kurdistan University of
Medical Sciences

Full name of responsible person

Vice Chancellor for research

Street address

Vice Chancellor for research, Kurdistan University of
Medical Science, Pasdaran street

City

Sanandaj

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 of Kurdistan University 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

Kurdistan University of Medical Sciences

Full name of responsible person

Sina Valiee

Position

PhD, Assistant Professor

Other areas of specialty/work

Street address

Kurdistan University of Medical Sciences, School of
Nursing and Midwifery

City

Sanandaj

Postal code

Phone

+98 87 3362 7228

Fax

+98 87 3366 0092

Email

SinaValiee@yahoo.com

Web page address

muk.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Behrooz Zarei

Position

Bachelor of Nursing

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Kurdistan University
of Medical Sciences, Pasdaran Street

City

Sanandaj

Postal code

6615733173

Phone

+98 87 3362 7228

Fax

Email

Behroozzareei62@yahoo.com ;

Behroozzareei62@muk.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Behrooz Zarei

Position

Bachelor of Nursing

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Kurdistan University
of Medical Sciences, Pasdaran Street

City

Sanandaj

Postal code**Phone**

+98 87 3323 2115

Fax

+98 33660092

Email

Behroozzare62@yahoo.com ;
Behroozzare62@muk.ac.ir

Web page address

muk.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty