

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Survey the effect of fluid therapy before Spinal Anesthesia on Reduction of Postural Puncture Headache in patients undergoing surgery.

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

Objectives: This study will perform for survey of the effect of hydrotherapy before spinal anesthesia on reduction of postdural puncture headache. **Design:** This study is a clinical trial on 80 patients who referred to operating room of Ghamar Hospital of Neyshabur for elective surgery under spinal anesthesia. Patients are randomly assigned to intervention or control groups. Randomization of patients is achieved using table of random numbers. **Setting and conduct:** After approval of the study by the Vice Chancellor for research of Neyshabur University of Medical Sciences and Ethics committee of Neyshabur University of Medical Sciences and getting informed consent, patients will enter to the study. The inclusion criteria for the study are not addiction, no history of migraine headache and use of spinal anesthesia techniques. Exclusion criteria are patient dissatisfaction and receiving different drugs or different doses on spinal anesthesia. **Intervention:** The patients will enter to the operating room without I.V line. Patients in intervention group will receive 500 ml Normal Saline before spinal anesthesia and patients in control group not receive normal saline before spinal anesthesia. Spinal anesthesia will perform by Bupivacaine plus Sufentanil injection using a spinal needle size of 27. **Main outcome measures:** Intensity of headache and backache in the patients in postoperative period will be examined by pain questionnaire in 4, 8, 24, 48 and 72 hour and 7 days after surgery on the phone. The interviewer will not know about the intervention and will be trained on evaluation of the existence of headache and backache among the patients.

Last update:

Update count: **0**

Registration date

2016-08-31, 1395/06/10

Registrant information

Name

Seyedeh Masoomeh Saadati

Name of organization / entity

Neyshabur University of Medical Science

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Neyshabur University of Medical Sciences

Expected recruitment start date

2016-08-07, 1395/05/17

Expected recruitment end date

2016-12-07, 1395/09/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of fluid therapy before Spinal Anesthesia on Reduction of Postural Puncture Headache in patients undergoing surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050727773N1**

Registration date: **2016-08-31, 1395/06/10**

Public title

The effect of fluid therapy on Postural Puncture Headache in patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: No addiction; No history of migraine headache; Spinal anesthesia. Exclusion criteria: Patient dissatisfaction; Receiving different drugs or different doses of drug for spinal anesthesia.

Age

From **20 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization of patients was achieved using table of random numbers.

Secondary Ids

empty

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

Ethics committee of Neyshapur University of Medical Sciences

Street address

Razi Street.Neyshapur

City

Neyshapur

Postal code

9314634814

Approval date

2016-04-20, 1395/02/01

Ethics committee reference number

IR.NUMS.REC.1394.16

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

-

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Postdural Puncture Headache

Timepoint

1 hour after intervention; 7 hour intervention; 24 hour after intervention; 7 days after intervention;

Method of measurement

Pain questionnaire

Secondary outcomes**1****Description**

backache

Timepoint

1 hour after intervention; 4 hour after intervention; 6 hour after intervention; 24 hour after intervention; 7 days after intervention

Method of measurement

Pain questionnaire

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

Intervention group: receive 500 ml of 0.9% normal saline 30 minute before surgery.

Category

Prevention

2**Description**

Control group: do not receive fluid therapy before spinal anesthesia.

Category

Prevention

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

Ghamar Hospital

Full name of responsible person

Dr Rasgoo

Street address

Ghamar Hospital, Imam Khomeini Street, Neyshapur

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Neyshapur University of Medical Science

Full name of responsible person

Seyedeh Masoomeh Saadati

Street address

Razi street, Neyshapur, Neyshapur university of Medical Science

City

Neyshbur

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, Neyshapur University of Medical Science

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**

Neyshapur University of Medical Sciences

Full name of responsible person

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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