

# 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

Iran (Islamic Republic of)

##### Phone

+98 513333964

##### Email address

saadatim2@nums.ac.ir

#### 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**

Seyedeh Masoomeh Saadati

**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

Razi street, Neyshapur University of Medical Sciences, Neyshapur,

**City**

Neyshpur

**Postal code**

93186-14139

**Phone**

+98 51433440

**Fax**

**Email**

saadati.msnursing@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Neyshapur university of medical sciences

**Full name of responsible person**

Seyedeh Masoomeh Saadati

**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

Razi Street, Neyshpur

**City**

Neyshapur

**Postal code**

**Phone**

+98 51433440

**Fax**

**Email**

saadati.msnursing@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Neyshapur university of medical sciences

**Full name of responsible person**

Seyedeh Masoomeh Saadati

**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

Razi Street, Neyshapur

**City**

Neyshbur

**Postal code**

93186-14139

**Phone**

+98 935 930 0224

**Fax**

**Email**

saadati.msnursing@gmail.com

**Web page address**

## 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*