Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050727773N1**

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

Registration timing: **registered_while_recruiting**

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

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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.

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 Neyshaspur 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, Neyshabur
City

Neyshapur

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Neyshabur University of Medical Science
Full name of responsible person
Seyedeh Masoomeh Saadati
Street address
Razi street, Neyshabur, Neyshabur university of Medical Science
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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,Neyshabur 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
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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