

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of prophylactic single dose of sublingual desmopressin on post dural puncture headache after spinal anesthesia.

Protocol summary

Summary

The aim of this study is evaluating the effect of prophylactic single dose of sublingual desmopressin on post dural puncture headache after spinal anesthesia. After taking letter of satisfaction from patients for desmopressin use and educating about VAS to evaluate headache severity, Patients will be divided into 2 groups: 1) study and 2) placebo. In study group patients will be receive one 60 micro gram Minirin melt tablet (sublingual) 10 minutes before spinal anesthesia. Inclusion criteria: 1) all 18-60 years old patients which are candidate for elective surgery by spinal anesthesia. 2) ASA I-II. Exclusion criteria: 1) history of migraine headache. 2) history of backache. 3) history of heart failure and renal failure. 4) history of hypertension. 5) history of spinal anesthesia or lumbar puncture in the recent month. 6) history of puncture more than two times. 7) history of high ICP. 8) electrolyte disturbance. 9) psychopathic condition. 10) other contraindications for spinal anesthesia such as local infection and coagulopathy. The questioner person who is a medicine student isn't aware of Minirin prescription. In placebo group patients will be received a piece of starch in the size of Minirin tablet. At the end ,per 24 hours during one week existence of headache and it's severity will be measured by VAS,if suffering headache, patients would receive therapy. The main variable in this study (headache severity) is a qualitative dependent variable. For parametric variables with normal distribution curve "independent T test" or "unpaired T test" and for parametric data with abnormal distribution "mann whitney" and for qualitative variables K square test² " and also about frequent measurements "repeated measures dependent variable test" will be used. Data will be studied by SPSS15 statistic software. $P < 0.05$ will be sensitive statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031416956N5**

Registration date: **2015-06-16, 1394/03/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-16, 1394/03/26

Registrant information

Name

Hassan Mohammadipour Anvari

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

dr.anvari22@yahoo.com

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-08-06, 1394/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prophylactic single dose of sublingual desmopressin on post dural puncture headache after spinal anesthesia.

Public title

Effect of desmopressin on post dural puncture headache after spinal anesthesia.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1) all 18-60 years old patients with are candidate for elective surgery by spinal anesthesia. 2)ASA I-II. Exclusion criteria: 1)history of migraine headache. 2)history of backache. 3)history of heart failure and renal failure. 4)history of hypertension. 5)history of spinal anesthesia or lumbar puncture in the recent month. 6)history of puncture more than two times. 7)history of high ICP. 8)electrolyte disturbance. 9)psychopathic condition. 10)other contraindications for spinal anesthesia such as local infection and coagulopathy.

Age

From **18 years** old to **60 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**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tabriz medicine university

Street address

Tabriz.university sq

City

Tabriz

Postal code**Approval date**

2014-09-23, 1393/07/01

Ethics committee reference number

9/4_4/2

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

The Post dural puncture headache after spinal anesthesia

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

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

Headache severity

Timepoint

Per 24 hours during one week

Method of measurement

By VAS

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

vomiting & nausea

Timepoint

Daily

Method of measurement

questionnaire

2**Description**

oedema

Timepoint

Daily

Method of measurement

questionnaire

3**Description**

hypertention

Timepoint

Daily

Method of measurement

questionnaire

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

Study group: Minirin tablet(60 micro gram)will give10

minute before spinal anesthesia

Category
Prevention

2

Description
Control group:a piece of starch will give before spinal anesthesia

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospitol

Full name of responsible person
Hassan Mohammadipour Anvari

Street address
Daneshgah sq

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sceinces

Full name of responsible person
Dr Hassan soleimanpour

Street address
Tabriz university of Medical Sceinces

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz University of Medical Sceinces

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

Tabriz University of Medical Sceinces

Full name of responsible person
Hassan Mohammadipoor Anvari

Position
Assistant professor

Other areas of specialty/work

Street address
Emam Reza hospital

City
Tabriz

Postal code

Phone
+98 41 3334 7054

Fax

Email
dr.anvari22@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sceices

Full name of responsible person
Hassan Mohammadipoor Anvari

Position
Assistant professor

Other areas of specialty/work

Street address
Emam Reza hospitol

City
Tabriz

Postal code

Phone
+98 41 3334 7054

Fax

Email
dr.anvari22@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hassan Mohammadipour Anvari

Position
Assistant professor

Other areas of specialty/work

Street address
Emam Reza hospitol

City
Tabriz

Postal code

Phone
+98 918 811 2210

Fax

Email

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