

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Effect of Prophylactic Hydrocortisone in Post Dural Puncture Headache after Spinal Anesthesia

#### Protocol summary

##### Summary

In this randomized, double blind trial we will investigate the effect of intravenous hydrocortisone in post dural puncture headache after spinal anesthesia. 80 patients men or women between 20 to 60 ages candidated for lower abdominal surgery will be recruited and randomly assigned into two groups (intervention/control). Inclusion criteria is surgery with spinal anaesthesia and exclusion criteria are patient incontinency, coagulation disorders and other contraindication. For patient in intervention group, hydrocortisone 200mg and for patients in control group, 4cc normal saline will be administered intravenous 15 minutes before spinal anesthesia. Probable headache intensity will be measured at the baseline, 12 hour, 24 hour, 48 hour and 1 week after intervention. The other complications will be assessed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201504067313N3**

Registration date: **2015-05-22, 1394/03/01**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-05-22, 1394/03/01

##### Registrant information

###### Name

Mirmohammadtaghi Mortazavi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3669 1953

###### Email address

mortazavimt@tbzmed.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Vice-chancellor for research- Tabriz University of Medical Sciences

###### Expected recruitment start date

2015-06-11, 1394/03/21

###### Expected recruitment end date

2015-12-31, 1394/10/10

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effect of Prophylactic Hydrocortisone in Post Dural Puncture Headache after Spinal Anesthesia

###### Public title

Effects of Prophylactic Hydrocortisone in Post Dural Puncture Headache

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

inclusion criteria: lower abdomen surgery (ASA I-II); age 15-60; indication for spinal anesthesia exclusion criteria: chronic consumption of analgesic; ASA III-VI; history of addiction and psychologic disorders; migraine

###### Age

From **15 years** old to **60 years** old

###### Gender

Both

###### Phase

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

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethic committee.Tabriz university of medical sciences

##### Street address

daneshgah avenue,tabriz medical university,medicine college

##### City

tabriz

##### Postal code

#### Approval date

2014-04-28, 1393/02/08

#### Ethics committee reference number

9325

## Health conditions studied

### 1

#### Description of health condition studied

postdural puncture headache

#### ICD-10 code

O74.5

#### ICD-10 code description

spinal and epidural anaesthesia-induced headache during labour and delivery

### 2

#### Description of health condition studied

postdural puncture headache

#### ICD-10 code

T88.5

#### ICD-10 code description

other complications of anesthesia

## Primary outcomes

### 1

#### Description

headache intensity

#### Timepoint

recovery,12,24,48 and one week after surgery

#### Method of measurement

VAS

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Amp hydrocortison 200mg will be administered bolus over 30 seconds intravenous 15 minutes before spinal anesthesia

#### Category

Treatment - Drugs

### 2

#### Description

4cc normal saline 15minute before spinal anesthesia will be administered intravenous.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

##### Full name of responsible person

Dr.M.Mortazavi

##### Street address

Tabriz University of Medical Sciences, Golgasht Avn, Kuye daneshga, Tabriz

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for research - Tabriz University of Medical Sciences

##### Full name of responsible person

mirmohammadtaghi mortazavi

##### Street address

Tabriz University of Medical sciences, Kuye daneshga avenue, Tabriz, eastern azarbayjan

##### City

tabriz

**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 - Tabriz 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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shohada Hospital  
**Full name of responsible person**  
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Assistant Professor  
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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*