Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 hydrocortison 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,hydrocortison 200mg and for patients in control group, 4cc normal sali. 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 assesed.

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

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Recruitment status

Recruitment complete

Funding source

Vice-chanceller 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; migrane

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 anasthesia

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 administerd bolus over 30 seconds intravenous 15 minutes before spinal anesthesia
Category
Treatment - Drugs

2

Description
4cc normal salin 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chanceller for research - Tabriz University of Medical Sciences
Full name of responsible person
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Tabriz University of Medical sciences, Kuye daneshga avenue, Tabriz, eastern azarbayjan
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chanceller 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

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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