

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of prophylactic single dose of Desoxy corticosterone acetate on post dural puncture headache after spinal anesthesia.

Protocol summary

Summary

Patients will be divided to 2 groups; study and placebo after taking the letter of satisfaction for controlling of headache due to surgery. In study group a DOCA ampule 5mg/cc will be injected a quarter before spinal anesthesia. The questioner person who is a medicine student isn't aware of DOCA injection. In placebo group normal saline 1 cc will be injected. At the end, per 24 hours during one week existence of headache and its severity will be measured by VAS. 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 chi square tests " 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: **IRCT2014113016956N3**

Registration date: **2015-05-26, 1394/03/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-26, 1394/03/05

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 medicine university

Expected recruitment start date

2015-05-18, 1394/02/28

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 Desoxy corticosterone acetate on post dural puncture headache after spinal anesthesia.

Public title

Effect of Desoxy corticosterone acetate on post dural puncture headache after spinal anesthesia.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all 18-60 years old patients candidate for elective general surgery by spinal anesthesia; ASA I-II. Exclusion criteria: the history of migraine headache; the history of backache; history of hypertension; history of spinal anesthesia or lumbar puncture in the recent month; history of lumbar puncture more than 2 times; history of high ICP; psychopathic condition; other instances for forbidding spinal anesthesia such as local infection and coagulopathy disorders; the use of Digoxin

and diuretics.

Age
From **17 years** old to **59 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

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 University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Daneshgah square

City
Tabriz

Postal code

Approval date
2014-03-10, 1392/12/19

Ethics committee reference number
92236

Health conditions studied

1

Description of health condition studied
The Post dural puncture Headache after spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Headache severity

Timepoint
Per 24 hours during one week

Method of measurement
By VAS

Secondary outcomes

1

Description
oedema

Timepoint
daily

Method of measurement
questionnaire

2

Description
vomiting & nausea

Timepoint
Daily

Method of measurement
Graded questionnaire

3

Description
diarrhea

Timepoint
daily

Method of measurement
questionnaire

Intervention groups

1

Description
In study group:a DOCA ampul 5mg/cc will be injected a quarter before spinal anesthesia.

Category
Prevention

2

Description
In control group:normal saline 1cc will be injected.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospital

Full name of responsible person
Hassan Mohammadipour Anvari

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hasan Mohhamadipoor Anvari

Street address

School of Medicine, Tabriz University of Medical Sciences

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 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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hassan Mohhamadipoor Anvari

Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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