Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of prophylactic effects of intravenous hydrocortisone on incidence and severity of post dural puncture headache after spinal anesthesia in comparison to control group

Protocol summary

Summary

Post-dural puncture headache was known as an unpleasant complication after spinal anesthesia. Release of inflammatory mediators from puncture site was described as a contributing factor in this headache. Anti-inflammatory drugs such as hydrocortisone can reduce inflammation and release of inflammatory mediators, so this study was designed to evaluate prophylactic effects of hydrocortisone on post-dural puncture headache. Seventy candidates of lower extremity and/or lower abdominal surgeries under spinal anesthesia allocate in two groups and in a double blind clinical trial take hydrocortisone (5mg/kg) or placebo, intravenously, 20 minutes before spinal anesthesia. Two groups compare for incidence and severity of headache, in first 3 days after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071216415N4**
Registration date: **2014-07-17, 1393/04/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-17, 1393/04/26

Registrant information

Name

Mohammad Golparvar

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-10-07, 1393/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prophylactic effects of intravenous hydrocortisone on incidence and severity of post dural puncture headache after spinal anesthesia in comparison to control group

Public title

Evaluation of effects of hydrocortisone on prevention of post spinal headache

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 15 to 65 years old; ASA 1 and 2; candidates of lower extremity or lower abdominal surgeries under spinal anesthesia; no history of migraine headache; no history of prescription of steroidal or non-steroidal anti-inflammatory drugs; without opiate addiction Exclusion criteria: Failure of spinal anesthesia

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Ethics comity of vice research of medical school of Isfahan university of medical sciences

Street address

Vice research of medical school, Isfahan University of Medical Sciences, Hezarjarib boulevard; Isfahan, Iran

City

Isfahan

Postal code

Approval date

2014-02-23, 1392/12/04

Ethics committee reference number

16260

Health conditions studied

1

Description of health condition studied

Post-dural puncture headache

ICD-10 code

Y56.0

ICD-10 code description

Local antifungal, anti-infective and anti-inflammatory drugs, not elsewhere classified

Primary outcomes

1

Description

Headache

Timepoint

2; 6; 12 and 48 hours after surgery

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Nausea and Vomitting

Timepoint

2; 6; 24 and 48 after surgery

Method of measurement

Visual Analog Scale (VAS)

Intervention groups

1

Description

Intervention: Prescription of intravenous hydrocortison 5 mg/kg

Category

Treatment - Drugs

2

Description

Control group: Normal saline as a placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Medical Center

Full name of responsible person

Golparvar M. MD

Street address

Department of Anesthesia, Alzahra Medical center, Sofeh boulevard, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and technology of Isfahan University of Medical Sciences

Full name of responsible person

Dr Alimohammad Sabzeghabaei

Street address

Research manager office, Deputy of research and

technology; Isfahan University of Medical Sciences; Hezarjarib Boulevard, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research and technology of Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Golparvar M MD

Position

Associate professor in Medical School of Isfahan University of Medical Sciences

Other areas of specialty/work

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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