Clinical Trial Protocol
Iranian Registry of Clinical Trials
28 Dec 2021

Effect of epidural dexamethasone on post dural puncture headache

Protocol summary

Summary
To determine the effect of epidural dexamethasone on post dural puncture headache, 268 patients who fulfilled the inclusion criteria were recruited: 1- Candidate for spinal anaesthesia 2- Age 18-40 years 3- ASA class I & II. Informed consent was obtained from all patients. In a double blind randomized controlled clinical trial, patient underwent spinal anaesthesia with 10 mg bupivacaine 0.5% in sitting position (the needle which was used was the Quincke No 27). The needle was withdrawn 0.5 -1 cm while barbotaging was maintained and when the CSF flux was stopped (which was the sign of epidural space) 2 ml dexamethasone (8 mg) in case group or 2 ml normal saline in control group was injected. Then the needle was withdrawn completely. All patients were followed for one week for any sign of post dural puncture headache or back pain.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201112178441N1
Registration date: 2012-01-07, 1390/10/17
Registration timing: registered_while_recruiting

Email address
semami@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source
Tehran University of medical sciences

Expected recruitment start date
2010-06-22, 1389/04/01

Expected recruitment end date
2012-01-21, 1390/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of epidural dexamethasone on post dural puncture headache

Public title
Effect of epidural dexamethasone on post dural puncture headache

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: 1-All patient candidate for spinal anesthesia; 2- age 18-40; 3-ASA class I & II. Exclusion criteria: 1- Migraine headache; 2-CNS malignancy; 3-Epilepsy; 4-systemic disease: HTN, cardiac arrhythmia, thyroid disease; 5- Psychiatric disorders; 6-Drug abuse; 7-Back pain.

Age
From 18 years old to 40 years old

Gender
Both

Phase
3

Groups that have been masked
Sample size
Target sample size: 268
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
Tehran University of Medical Sciences
Street address
Ghods street, Keshavarz Boulevard
City
Tehran
Postal code
Approval date
2011-11-28, 1390/09/07
Ethics committee reference number
130/1586/90/

Health conditions studied

1
Description of health condition studied
post dural puncture headache
ICD-10 code
G97.1
ICD-10 code description
Other reaction to spinal and lumbar puncture

Primary outcomes

1
Description
headache
Timepoint
24 hours, 48 hours, 7 days
Method of measurement
classification of Severity of Meningeal Puncture Headache (MPH)

Secondary outcomes

1
Description
Backpain
Timepoint
24 hours, 48 hours, 7 days
Method of measurement
Patient complaint

Intervention groups

1
Description
Intervention: patient underwent spinal anaesthesia with 10 mg bupivacaine 0.5% in sitting position (the needle which was used was the Quincke No 27). The needle was withdrawn 0.5 -1 cm while barbotaging was maintained and when the CSF flux was stopped (which was the sign of epidural space) 2 ml dexamethasone (8 mg) was injected. Then the needle was withdrawn completely.
Category
Prevention

2
Description
Control: patient underwent spinal anaesthesia with 10 mg bupivacaine 0.5% in sitting position (the needle which was used was the Quincke No 27). The needle was withdrawn 0.5 -1 cm while barbotaging was maintained and when the CSF flux was stopped (which was the sign of epidural space) 2 ml normal saline was injected. Then the needle was withdrawn completely.
Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Dr Sara Emami
Street address
Imam khomeini Ave.
City
Teharn

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
Dr Akbar Fotoohi
Street address
Ghods street, Keshavarz blvd.
City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of medical sciences
Full name of responsible person
Dr Sara Emami
Position
Assistant
Other areas of specialty/work

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
Dr Atabak Nadjafi
Position
Associate Professor
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