Effect of intravenous Propofol on post-dural puncture headache

Protocol summary

Summary
The purpose of this study os to investigate the effect of intravenous Propofol on post-dural puncture headache. 40 patients with post dural puncture headache are enrolled. They are randomly divided into two groups. The control group receives conventional therapy including fluid and oral Acetaminophen while the intervention group will receive fluid and subanesthetic dose of intravenous propofol. They will receive rescue therapy with intravenous meperidine or epidural blood patch as needed. Pain score will be compared among these two groups.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138812083437N1
Registration date: 2010-06-18, 1389/03/28
Registration timing: registered_while_recruiting

Last update:
Update count: 0
Registration date
2010-06-18, 1389/03/28

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source
Anesthesiology Research Center

Expected recruitment start date
2010-03-21, 1389/01/01
Expected recruitment end date
2011-12-22, 1390/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of intravenous Propofol on post-dural puncture headache

Public title
Effect of intravenous Propofol on post-dural puncture headache

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: suffering from post-dural puncture headache, ASA class 1 and 2, not received intravenous therapy except fluid for their current headache, headache started within last 48 hours Exclusion criteria: Patients with ASA classes other than 1 and 2, receiving intravenous treatment, drug addiction

Age
From 14 years old to 60 years old

Gender
Both

Phase
0
Groups that have been masked
None

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
**Secondary Ids**
empty

**Ethics committees**

1

**Ethics committee**

Name of ethics committee
Shaheed Beheshti Medical University
Street address
Velenjak
City
Tehran
Country
Iran (Islamic Republic of)
Postal code
Approval date
2010-03-19, 1388/12/28
Ethics committee reference number
00123

**Health conditions studied**

1

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

**Primary outcomes**

1

Description
pain
Timepoint
Every 5 minutes until 24 hours
Method of measurement
VAS

**Secondary outcomes**

1

Description
opioid need
Timepoint
Every 5 minutes until 24 hours
Method of measurement
mg of pethidine needed to reduce pain to less than 3 (VAS)

**Intervention groups**

1

Description
acetaminophen (500 mg oral every 4 hour for 24 hours)
Category
Treatment - Drugs

2

Description
propofol (1 mg/kg/h IV infusion for 30 minutes every 6 h till 24 hour)
Category
Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

Name of recruitment center
Anesthesiology Research Center
Full name of responsible person
Hedayatollah Elyassi
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**Sponsors / Funding sources**

1

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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
Anesthesiology Research Center
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
Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
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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