Effect of intravenous Propofol on post-dural puncture headache

Protocol summary

Summary
The purpose of this study is 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

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
No information

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
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 untill 24 hours
Method of measurement
VAS

Secondary outcomes

1
Description
opioid need
Timepoint

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
Street address
Anesthesiology Research Center,Taleghani Hospital, Velenjak
City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Anesthesiology Research Center
Full name of responsible person
Hedayatollah Elyassi
Street address
Anesthesiology Research Center,Taleghani Hospital, Velenjak
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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
Person responsible for general inquiries

Contact
Name of organization / entity
Anesthesiology Research Center
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