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 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 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**
   - **Street address**
     - 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
   - **City**
     - Tehran

**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**

---
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Anesthesiology Research Center
Full name of responsible person
Hedayatollah Elyassi
Position
Professor
Other areas of specialty/work
Street address
Anesthesiology Research Center, Taleghani Hospital, Velenjak
City
Tehran
Postal code
Phone
+98 21 2243 2572
Fax
Email
a.r.c@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Anesthesiology Research Center
Full name of responsible person
Hedayatollah Elyassi
Position
Professor
Other areas of specialty/work
Street address
Anesthesiology Research Center, Taleghani Hospital, Velenjak
City
Tehran
Postal code
Phone
+98 21 2243 2572
Fax
Email
a.r.c@sbmu.ac.ir
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