Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Frequency of post spinal headache and some of related factors

Protocol summary

Summary

This study was an interventional study. After approval the project, all patients candidate for surgery referred to academic hospitals affiliated to Babol University of Medical Sciences and spinal anesthesia was done for them, considered as the study population. All of the referal patients donot have criteria for arriving to our investigation so ,three hundred patients were recruited in the study by simple randomized method. Those with a contraindication of LP were excluded. Five to 7 mlit/kg crystalloid were prescribed before spinal anesthesia. Anesthesia was done in semisitting position, in L3 to S1 intraspinal space with a size 25 needle (G25). Then patient goes as supine position and after reaching to a sufficient anesthesia level, operation would be started. Dexamethasone 8 miligrams, Midasolam 1-2 miligrams or Fentanyle 1.5-2 micrograms per body weight were used after spinal anesthesia regards to the age and type of surgery. CSF fluid situation, intraspinal space used for spinal anesthesia, type and amount of infused drugs into intratecal space, liquid supplementation and type of surgery were recorded in a checklist. During the spinal anesthesia, vital signs were checked for all and recorded. All patients were followed up to a week after discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203113305N3**
Registration date: **2012-05-30, 1391/03/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-05-30, 1391/03/10

Registrant information

Name

Ebrahim Alijanpour

Name of organization / entity

Babol University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University Of Medical Science

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Frequency of post spinal headache and some of related factors

Public title

Frequency of post spinal headache and some of related factors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: All patients candidate for surgery referred to academic hospitals affiliated to Babol University of Medical Sciences and accepted to use spinal anesthesia Exclusion criteria: Contraindications for LP, psychotic patients or brain space- occupying lesions

Age

No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol University Of Medical Sciences

Street address
Daneshgah Sq - Ganjafrooz St

City
Babol

Postal code

Approval date
2012-05-01, 1391/02/12

Ethics committee reference number
6266/30/پ/ژ

Health conditions studied

1

Description of health condition studied
post spinal headache

ICD-10 code
G44.8

ICD-10 code description
Other specified headache syndromes

Primary outcomes

1

Description
headache

Timepoint
daily

Method of measurement
question & answer(check list)

Secondary outcomes

empty

Intervention groups

1

Description
After the presentation of post spinal headache, signs & symptoms; it will be treated according to the severity by prescription medicine in out or in patients form. For out-patients NSAIDs, Caffeine & Dexamethasone will prescribe. For in-patient's Blood epidural Patch and serum therapy will be done. For example Cap Novafen (300mg Acetaminophen, 200mg Ibuprofen, and 80mg caffeine) will be drug of choice.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Dr Ebrahim Alijanpour

Street address

City
Babol

2

Recruitment center

Name of recruitment center
Ayatollah Ruhani Hospital

Full name of responsible person
Dr Ebrahim Alijanpour

Street address

City
Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor Of Research Babol University Of Medical Science

Full name of responsible person
Dr Amrolah Mostafazadeh

Street address
Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

City
Babol

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor Of Research Babol University Of Medical Science
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
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Full name of responsible person
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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