Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of voluven on post spinal headache in patients with cesarean section

Protocol summary

Summary

5-7ml/kg Voluven was administered in 100 patients of the trial group who where candidates of cesarean section with spinal anesthesia. In order to evaluate the effect of voluven. Administration in incidence rate of post spinal headache and evaluated PSH daily until one week post spinal headache. Patients contraindicated of LP; psychotic or patients with space occupying lesion; addicts; corticosteroid and NSAID users.In control group patients ,5-7ml/kg ringer serum was administered and incidence rate of headache was evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308243305N5**
Registration date: **2014-12-20, 1393/09/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-20, 1393/09/29

Registrant information

Name

Ebrahim Alijanpour

Name of organization / entity

Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Babol University Of Medical Sciences

Expected recruitment start date

2013-07-11, 1392/04/20

Expected recruitment end date

2014-09-11, 1393/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of voluven on post spinal headache in patients with cesarean section

Public title

Effect of voluven on post spinal headache in patients with cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: All of patients who are candidates for Cesarean section with Spinal anesthesia. Exclusion Criteria: Patients contraindicated of LP; psychotic or patients with space occupying lesion; addicts; corticosteroid and NSAID users.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University Of Medical Sciences
Street address
Daneshgah Square, Ganjafrooz Avenue
City
Babol
Postal code
Approval date
2013-07-02, 1392/04/11
Ethics committee reference number
2726/30/ژ/پ

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 until one week post spinal headache
Method of measurement
Question & answer

Secondary outcomes

1

Description
Blood pressure
Timepoint
During spinal anesthesia
Method of measurement
BP Cuff

2

Description
Heart rate
Timepoint
During spinal anesthesia
Method of measurement
ECG

3

Description
Nausea & Vomiting
Timepoint
During spinal anesthesia
Method of measurement
Question & answer

4

Description
Arterial oxygen saturation
Timepoint
During spinal anesthesia
Method of measurement
pulse oximeter

Intervention groups

1

Description
Intervention: administration of 5-7ml/kg voluven after spinal anesthesia
Category
Prevention

2

Description
Control:administration of 5-7ml/kg ringer serum after spinal anesthesia
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Ruhani Hospital
Full name of responsible person
Dr Ebrahim ALijanpour
Street address
Daneshgah Square, Ganjafrooz Avenue
City
Babol

2

Recruitment center
Name of recruitment center
shahid Beheshti Hospital
Full name of responsible person
Dr Ebrahim Alijanpour
Street address
shahid ghasemi Avenue
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor Of Research Babol University Of Medical Sciences
Full name of responsible person
Dr Aliakbar Moghadamnia
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 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
Babol University Of Medical Sciences
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Dr Ebrahim Alijanpour
Position
Associate Professor of Anesthesiology
Other areas of specialty/work
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Person responsible for updating data

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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