

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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 were 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1228 0013

##### Email address

dralijanpour@mubabol.ac.ir

##### 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/ز/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

**Full name of responsible person**

Dr Ebrahim Alijanpour

**Position**

Associate Professor of Anesthesiology

**Other areas of specialty/work**

**Street address**

Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Email**

**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*