

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

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Email address

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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/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

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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