Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of gabapentin plus vitamin B - complex and gabapentin alone on pain after spinal anesthesia for cesarean section

Protocol summary

Summary

The aim of study was to compare the effects of gabapentin and gabapentin plus B-Complex -induced analgesia in reducing pain after cesarean section . In this study, pregnant women undergoing cesarean section from 17 to 40 years old who have not underlying medical condition involved. in This double-blind study of 128 patients in two groups: one group of 64 people who gabapentin 300 mg and other group 300mg gabapentin plus B-Complex a half hour before cesarean received .The requirement for analgesia including diclofenac and pethidine is assessed. VPS, sleepy, and vomiting at recovery and 2, 4, 8 and 12 hours after a cesarean section is investigated. All patients received 2.5 mg of bupivacaine 0.5% with a spinal needle placed No. 25 Quinke under spinal anesthesia.. .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040617138N1**
Registration date: **2014-09-21, 1393/06/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-21, 1393/06/30

Registrant information

Name

Ghodrat Allah Soltanian

Name of organization / entity

Ghazvin University of Medical Science

Country

Iran (Islamic Republic of)

Phone

00283359557

Email address

ghsoltanian@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Gazvin University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-09-16, 1392/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of gabapentin plus vitamin B - complex and gabapentin alone on pain after spinal anesthesia for cesarean section

Public title

Effect of Vitamin B-Complexand gabapentin in reducing pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women undergoing cesarean section between 17 and 40 years old; Patient satisfaction; The absence of an underlying disease, such as heart or lung disease, and seizures; No previous frequent use of analgesics; Lack of drug addiction; Exclusion criteria: pregnant women undergoing cesarean section are less than 17 years and has more than 40 years; Lack of consent; Underlying disease, such as heart or lung disease, and seizures; Previous repeated use analgesics; Drug Addiction

Age

From **17 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
N/A

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
Ghazvin University of Medical Science

Street address
Bahonar Blvd, Qazvin

City
Ghazvin

Postal code

Approval date
2013-11-25, 1392/09/04

Ethics committee reference number
28/20/8102

Health conditions studied

1

Description of health condition studied
Post operative pain

ICD-10 code
O74.9

ICD-10 code description
Complication of anaesthesia during labour and delivery, unspecified

Primary outcomes

1

Description
post operative pain

Timepoint
12 hour after operation

Method of measurement
observation

2

Description
Analgesic demands

Timepoint
First 12 hours

Method of measurement
milligram

Secondary outcomes

1

Description
sleepy

Timepoint
12 hour after operation

Method of measurement
ramsay score scale

2

Description
nausea and vomiting

Timepoint
12 hour after operation

Method of measurement
Require treatment and no treatment is needed.

Intervention groups

1

Description
All the patient in control group receive gabapentin 300 mg and two B-complex tablets orally half an hour before surgery to postoperative analgesia

Category
Treatment - Drugs

2

Description
In case group all the patients receive gabapentin 300 mg orally half an hour before surgery to postoperative analgesia

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kosar Hospital Ghazvin

Full name of responsible person
Ghodrat Allah Soltanian

Street address
City
Ghazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghazvin University of Medical Science
Full name of responsible person
Godrat Allah Soltanian
Street address
Kosar Hospital Ghazvin
City
Ghazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghazvin 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
Ghazvin University of Medical Science
Full name of responsible person
Nahid Naseh
Position
Assistant professor
Other areas of specialty/work
Street address
Kosar Hospital Ghazvin
City
Ghazvin
Postal code
Phone
+98 28 3379 0621
Fax
Email
nahid.nasseh@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ghazvin University of Medical Sciences
Full name of responsible person
Nahid Nahid
Position
Assistant professor
Other areas of specialty/work
Street address
Kosar Hospital Ghazvin
City
Ghazvin
Postal code
Phone
+98 28 3379 0621
Fax
Email
nahid.nasseh@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ghazvin University of Medical Science
Full name of responsible person
Nahid Naseh
Position
Assistant professor
Other areas of specialty/work
Street address
Kosar Hospital Ghazvin
City
Ghazvin
Postal code
Phone
+98 28 3379 0621
Fax
Email
nahid.nasseh@yahoo.com
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