

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The efficacy of gabapentin after cesarean section in reducing post-cesarean pain in women with elective cesarean section and spinal anesthesia

Protocol summary

Summary

The aim of this study was to evaluate the effectiveness of gabapentin in reducing pain after cesarean section in order to reduce the use of narcotic drugs, which is randomized, double blind, post-marketing, single-center, stage two trials. In this study, participants are randomly categorized in separate groups, thus allowing comparison of interventions to the researcher. Patients under study, women referring to health center, educational, research martyrs Mobini Sabzevar, who intends to have elective cesarean section. The main inclusion criteria are: Pregnant women with term pregnancy: spinal anesthesia: aged over eighteen years old: with pfannenstiel incision case in previous cesarean section: live and single fetus. The main exclusion criteria included: need general anesthesia: analgesic use 8 hours before surgery: use non-steroidal anti-inflammatory drugs 24 hours before surgery, and the patients are divided into two groups of 51, comprising the control group (1 placebo capsule) and the intervention group (1 capsule gabapentin 300 mg). Both groups receive oral medication, then cesarean section. The main study is pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081635740N1**
Registration date: **2017-09-17, 1396/06/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-17, 1396/06/26

Registrant information

Name

sara hajiseyedi

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44011000051

Email address

hajiseyedis88@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2017-08-22, 1396/05/31

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of gabapentin after cesarean section in reducing post-cesarean pain in women with elective cesarean section and spinal anesthesia

Public title

Effect of gabapentin in post-cesarean pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who were willing to participate in the study and signed an informed consent letter; age

18 and above; Pregnancy age between 37 and 42 weeks; Term pregnancy; Having a live and monolingual fetus; Auxillary tempreture less than 37.5 degrees; Pfannenstiel incision in the previous cesarean section; Elective cesarean; Spinal anesthesia; No history of seizure; No history of gabapentin susceptibility; No history of psychiatric disorders; No Infectious Disease AIDS and hepatitis; Absence of uncontrolled blood pressure and diabetes; No systemic disease to moderate to severe; No alcohol and drug addiction. Exclusion criteria: Patient's lack of cooperation; Analgesic use 8 hours before surgery; Use of non-steroidal anti-inflammatory drugs 24 hours before surgery; Need for general anesthetic.

Age

From **77 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Sabzevar University of Medical Sciences and Health Services

Street address

Central Organization of Medical Sciences, Asad Abadi Street, sabzevar

City

Sabzevar

Postal code**Approval date**

2017-06-12, 1396/03/22

Ethics committee reference number

IR.MEDSAB.REC.1396.12

Health conditions studied**1****Description of health condition studied**

Pain after cesarean section

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain after cesarean section

Timepoint

6 times in recovery and at hours 2, 4, 6, 12, 24 after cesarean section

Method of measurement

Visual Scale of Pain

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group: gabapentin, 300 mg capsule, oral, single dose, Mehr Pharmaceutical Company

Category

Treatment - Drugs

2**Description**

In the control group: placebo, oral, single dose, capsule

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahidan Mobini Hospital

Full name of responsible person**Street address**

North Kashefi Avenue, Sabzevar

City

Sabzevar

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of sabzevar University of Medical Science

Full name of responsible person

Ms. Elham Bashtani

Street address

Vice Chancellor for research, near to trooper,
sabzevar

City

Sabzevar

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

M.s Sara Hajiseyedi

Position

Medical student

Other areas of specialty/work

Street address

Central Organization of Medical Sciences, Asad Abadi
Street, sabzevar

City

Sabzevar

Postal code

Phone

+98 51 4401 1000

Fax

Email

info@medsab.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mrs. Behnaz Sovizi

Position

Obstetricians

Other areas of specialty/work

Street address

Central Organization of Medical Sciences, Asad Abadi
Street, Sabzevar

City

Sabzevar

Postal code

Phone

+98 51 4401 1000

Fax

Email

info@medsab.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Sara Hajiseyedi

Position

medical student

Other areas of specialty/work

Street address

Central Organization of the University of Medical
Sciences, Asad Abadi Street, sabzevar

City

Sabzevar

Postal code

Phone

+98 51 4426 4462

Fax

Email

hajiseyedisara@gmail.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