Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of oral gabapentin versus placebo on pain relief after gynecologic surgery: a triple blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of oral gabapentin versus placebo on pain relief after gynecologic surgery. Design: A triple blinded randomized clinical trial. Setting and conduct: All eligible patients candidate for gynecologic surgery with hypogastric incision (hysterectomy, myomectomy, and ovarian cyst) who will refer to clinic of Besat Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a) age of 18 to 65 years; (b) women with physical class ASA I-II; (c) candidate for elective gynecologic surgery. Exclusion criteria: (a) contraindication for neuroaxial anesthesia; (b) history of hypertension or diabetes mellitus; (c) using narcotics or psychotropic. Intervention: (a) 34 patients will receive two gabapentin capsules 300 mg (600 mg) single dose 2 hours before surgery; (b) 34 patients will receive one gabapentin capsule 300 mg plus one placebo capsule (containing starch) single dose 2 hours before surgery. Control: 34 patients will receive two placebo capsules (containing starch) single dose 2 hours before surgery. Primary outcome: (a) pain severity at surgical site at 1, 6, 12, 18, 24, and 48 hours after surgery using VAS scale; (b) the amount of narcotic used during the first 48 hours after surgery per mg; (c) the duration of time to receive narcotic the first narcotic during the first 48 hours after surgery per min. Secondary outcome: (a) vertigo at 1, 6, 12, 18, 24, and 48 hours after surgery by question; (b) nausea and vomiting at 1, 6, 12, 18, 24, and 48 hours after surgery by question; (c) pruritus at 1, 6, 12, 18, 24, and 48 hours after surgery by question.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402289014N28**
Registration date: **2014-05-26, 1393/03/05**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2014-05-26, 1393/03/05

Registrant information

Name
Jalal Poorolajal
Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 81 1838 0090
Email address
poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral gabapentin versus placebo on pain relief after gynecologic surgery: a triple blinded randomized clinical trial

Public title

Effect of oral gabapentin versus placebo on pain relief

after gynecologic surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: (a) age of 18 to 65 years; (b) women with physical class ASA I-II; (c) candidate for elective gynecologic surgery. Exclusion criteria: (a) contraindication for neuroaxial anesthesia; (b) history of hypertension or diabetes mellitus; (c) using narcotics or psychotropic.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization: The patients will be assign randomly to one the three trial groups using balance block randomization with the block of six. Blinding: The patients will receive capsules with the same shape but different content (gabapentin or starch), thus, they will not aware of the intervention. In addition, the physician who will examine the patients and the analyzer who will perform the data analysis will not aware of the intervention. Therefore, the study will be run triple blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2014-05-17, 1393/02/27

Ethics committee reference number
P/16/35/9/711

Health conditions studied

1

Description of health condition studied
Pain at surgical site at inguinal area

ICD-10 code
R10.3

ICD-10 code description
Pain localized to other parts of lower abdomen

Primary outcomes

1

Description
Pain at the surgical site

Timepoint
at 1, 6, 12, 18, 24, and 48 hours after surgery

Method of measurement
using VAS scale

2

Description
the amount of narcotic used

Timepoint
during the first 48 hours after surgery

Method of measurement
per mg

3

Description
the duration of time to receive narcotic

Timepoint
during the first 48 hours after surgery

Method of measurement
per min

Secondary outcomes

1

Description
vertigo

Timepoint
at 1, 6, 12, 18, 24, and 48 hours after surgery

Method of measurement
by question

2

Description
nausea and vomiting

Timepoint
at 1, 6, 12, 18, 24, and 48 hours after surgery

Method of measurement
by question

3

Description
pruritus
Timepoint
at 1, 6, 12, 18, 24, and 48 hours after surgery
Method of measurement
by question

Intervention groups

1

Description
34 patients will receive two gabapentin capsules 300 mg (600 mg) single dose 2 hours before surgery
Category
Treatment - Drugs

2

Description
34 patients will receive one gabapentin capsule 300 mg plus one placebo capsule (containing starch) single dose 2 hours before surgery
Category
Treatment - Drugs

3

Description
34 patients will receive two placebo capsules (containing starch) single dose 2 hours before surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beasat Hospital
Full name of responsible person
Dr Parisa Shirzad
Street address
Beasat Hospital, Shahed Square
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
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 the Technology, Hamadan 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
Beasat Hospital
Full name of responsible person
Dr Parisa Shirzad
Position
Resident of Anesthesiology
Other areas of specialty/work
Street address
Beasat Hospital, Shahed Square
City
Hamadan
Postal code
Phone
+98 81 1341 6392
Fax
Email
shirzad.parisa7@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Beasat Hospital
Full name of responsible person
Dr Seyyed Mohammad Zolhavarieh
Position
Anesthesiologist
Other areas of specialty/work
Street address
Beasat Hospital, Shahed Square
City

Hamadan

Postal code

Phone

+98 81 1341 6392

Fax

Email

dsmbszolhavarieh@yahoo.com

Web page address

Person responsible for updating data

Contact

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