

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Perioperative Gabapentin for Prevention and Attenuation of Postoperative Shoulder Pain After Laparoscopic ovarian cystectomy

#### Protocol summary

##### Summary

Background: Shoulder pain after laparoscopic procedures is a frequent complication encountered in Gynecology ward. It is provoked by irritation or injury of the phrenic nerve at the diaphragm surface during CO<sub>2</sub> pneumoperitoneum. Several treatments have been proposed to reduce post laparoscopic shoulder pain. Gabapentin is one of these treatments which was effective in post laparoscopic pain reduction. The prepose of this study is to evaluate the efficacy of perioperative Gabapentin in preventing and attenuating PLSP after laparoscopic ovarian cystectomy. Material and methods: This is a prospective, randomized, double-blind study. 40 patients undergoing elective laparoscopic ovarian cystectomy in Women hospital Tehran University of medical science were enrolled in our study from April 2008 to march 2009 according to the inclusion and exclusion criteria. The control group received oral placebo capsules and case group 600 mg Gabapentin 0.5 h before surgery. The intensity of post laparoscopic shoulder pain (PLSP) was recorded by patient using a visual analogue scale (VAS) 2, 6, 12 hours post anesthetic recovery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201103166076N1**  
Registration date: **2011-04-26, 1390/02/06**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-26, 1390/02/06

##### Registrant information

##### Name

Sakineh Banifatemi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3318 7924

##### Email address

banifatemi.s@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Science

##### Expected recruitment start date

2008-09-22, 1387/07/01

##### Expected recruitment end date

2010-09-23, 1389/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Perioperative Gabapentin for Prevention and Attenuation of Postoperative Shoulder Pain After Laparoscopic ovarian cystectomy

##### Public title

Perioperative Gabapentin for Prevention and Attenuation of Postoperative Shoulder Pain After Laparoscopic ovarian cystectomy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

trial inclusion: patients 1- aged between 18 and70 2- of ASA (American Society of Anesthesia) physical status I-II 3- undergoing elective laparoscopic ovarian cystectomy

were enrolled in our study Trial exclusions: 1) hypersensitivity to any study drugs 2) serious organ disease/dysfunction 3) persistent preoperative pain 4) daily intake, or intake 48 h preoperatively, of any analgesic 5) alcohol/substance abuse 6) a major psychiatric disorder 7) a bleeding disorder 8) peptic ulcer disease 9) asthma/COPD 10) a seizure disorder 11) previous abdominal surgery

### Age

From **18 years** old to **70 years** old

### Gender

Female

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

### 1

#### Registry name

Australian New Zealand Clinical Trials Registry

#### Secondary trial Id

ACTRN12611000269932

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Science Ethics Committee

##### Street address

central organization of tehran university, 16th azar st. Enghelab Ave.

##### City

Tehran

##### Postal code

#### Approval date

2011-03-05, 1389/12/14

#### Ethics committee reference number

1578/130/89/ۛ

## Health conditions studied

### 1

#### Description of health condition studied

Laparoscopy - Ovarian Cyst

#### ICD-10 code

N80.1

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

2, 6, 12 hours post anesthetic recovery

#### Method of measurement

visual analogue scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

control : Placebo 600mg as premedication

#### Category

Placebo

### 2

#### Description

Drug : Gabapentin 600mg Gabapentin as premedication

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mirzakoochek khan Women Hospital

##### Full name of responsible person

##### Street address

Nejatolahi St. Karimkhan Ave.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Science

**Full name of responsible person**

Miss Rahmani

**Street address**Research administration of tehran university of  
medical sciences- Ghods Avenue-Keshavarz Blvd-  
Tehran-IRAN**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Sakineh Banifatemi

**Position**

Resident of Obstetrics and Gynecology

**Other areas of specialty/work****Street address**

No. 17-4th imam hasan All. Nabard St. Piroozi Ave.

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**Postal code**

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tamehrparidan\_56@yahoo.com**Web page address****Person responsible for scientific  
inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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m**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*