

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jul 2026

### Study of Pregabalin Effect on Post Surgical Pain on Breast Cancer Patients Underwent Axillary Dissection: a Double Blind Randomized Clinical Trial Using Placebo

#### Protocol summary

##### Study aim

Evaluating Pregabalin effect on post surgical patients who underwent breast cancer surgery

##### Design

Clinical trial with control group, Parallel groups, double blinded, randomized, phase 3, on 150 patients, Randomization was based on Random allocation software

##### Settings and conduct

Place: Shariati hospital and Imam Khomeini cancer institute Procedure: Patients scheduled for breast surgery were given 75 mg pregabalin or placebo 1h before surgery and continued every 12 h for 15 days. Pain scores were obtained using Verbal numerical rating scale at specific times after surgery. Patients and researcher were blinded toward the drug. only pharmacotherapist knew the code of the drugs. it was revealed after data gathering.

##### Participants/Inclusion and exclusion criteria

Patients who underwent breast cancer surgery were enrolled in the study. Patients who didn't sign the consent or with history of seizure or previously using pregabalin or GFR less than 60 or patients who were unable to cooperate with data gathering were excluded.

##### Intervention groups

Intervention group: 75 mg Pregabalin twice daily 15 days following surgery control group: 75 mg Placebo twice daily 15 days following surgery

##### Main outcome variables

Age! BMI! Morphine usage! surgery time! tumor size! Lymph node involvement! Hospital! Nausea! headache! Dizziness! blurred vision! neoadjuvant! Breast surgery type! Axillary surgery type! Addiction! Point of maximal pain! Pain scores at rest and arm abduction in 24h, 48h, 1w, 1M and 6 month after surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200502047263N1**

Registration date: **2020-05-08, 1399/02/19**

Registration timing: **retrospective**

Last update: **2020-09-27, 1399/07/06**

Update count: **1**

##### Registration date

2020-05-08, 1399/02/19

##### Registrant information

##### Name

Mohammad Masoomzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3668 3368

##### Email address

mzmasoomzadeh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2019-09-22, 1398/06/31

##### Actual recruitment start date

2019-07-14, 1398/04/23

##### Actual recruitment end date

2019-10-02, 1398/07/10

##### Trial completion date

2020-03-29, 1399/01/10

## Scientific title

Study of Pregabalin Effect on Post Surgical Pain on Breast Cancer Patients Underwent Axillary Dissection: a Double Blind Randomized Clinical Trial Using Placebo

## Public title

Study of Pregabalin effect on breast cancer surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients who underwent breast cancer surgery at Shariati hospital and Imam khomeini Cancer institute in 2019

### Exclusion criteria:

Patient denial to participate in the study Known cases with sensitivity to pregabalin History of seizure Patients who were already using Pregabalin or gabapentin or opioids Patients who were unable to cooperate with data gathering, physically or emotionally GFR less than 60

## Age

No age limit

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator

## Sample size

Target sample size: **250**

Actual sample size reached: **150**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization Method: Simple, each Patient has equal odds to be placed in intervention group or control group Randomization unit: Each patient No randomization layers was used randomization tool: Random allocation software Randomization sequence was created by software after defining each group and sample size allocation concealment: central telephone randomization system, researcher telephone the pharmacotherapist and asks what group next patient will be.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients, Researcher, Doctors and nurses and Data gatherers were blind towards the drug. Evaluator and analyzer were not blind.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran university of Medical Sciences

##### Street address

No 68, North Sindokht street, North Kargar Street, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1411933886

#### Approval date

2018-11-05, 1397/08/14

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.570

## Health conditions studied

### 1

#### Description of health condition studied

Post op Pain after breast cancer surgery

#### ICD-10 code

C50

#### ICD-10 code description

Malignant neoplasm of breast

## Primary outcomes

### 1

#### Description

Post op pain score after breast cancer surgery

#### Timepoint

24h, 48h, 1w, 1m and 6 month after surgery

#### Method of measurement

Verbal Numerical Rating Scale (VNRS)

## Secondary outcomes

### 1

#### Description

Morphine usage

#### Timepoint

after surgery until discharge

#### Method of measurement

nurse's report

## Intervention groups

### 1

#### Description

Intervention group: 75 mg Pregabalin 1h before surgery

orally then every 12h until 15 days after surgery

**Category**

Rehabilitation

**2**

**Description**

Control group: 75 mg Placebo 1h before surgery orally then every 12h until 15 days after surgery

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shariati Hospital, Imam Khomeini cancer institute

**Full name of responsible person**

Mohammad Masoomzadeh

**Street address**

No. 68, North Sindokht street, North Kargar street, Tehran

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**Province**

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**Postal code**

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**Phone**

+98 31 3668 3368

**Email**

Mzmasoomzadeh@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Masoomzadeh

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Tehran university of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Masoomzadeh

**Position**

General Surgery Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences

**Full name of responsible person**  
Mohammad Masoomzadeh

**Position**  
General Surgery Resident

**Latest degree**  
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**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data after concealment of the name can be shared

### When the data will become available and for how long

6 Month after publication

### To whom data/document is available

Researchers in scientific centers

### Under which criteria data/document could be used

Every usage or analysis on the data is permitted with mentioning the source. Requests are sent through email

### From where data/document is obtainable

Send request to Dr. Mohammad Masoomzadeh through email address: mzmasoomzadeh@yahoo.com

### What processes are involved for a request to access data/document

Send request email. I will respond within a week.

### Comments

## Trial results

### Please tick if results have been published

Yes

### Summary result posting date

2020-09-27, 1399/07/06

### Table of baseline comparison

| Basic characteristics    | Pregabalin group | Placebo group | P-Value |
|--------------------------|------------------|---------------|---------|
| Intention to treat       | N = 75           | N = 75        |         |
| Age (years)              | 51.31 ± 11.57    | 49.08 ± 11.40 | .226    |
| BMI                      | 29.49 ± 5.09     | 28.97 ± 4.29  | .211    |
| Hospital                 |                  |               |         |
| Shariati                 | 7 (9.3%)         | 14 (18.7%)    | .157    |
| IKHC                     | 68 (90.7%)       | 61 (81.3%)    |         |
| Neoadjuvant              |                  |               |         |
| Yes                      | 34 (45.3%)       | 22 (29.3%)    | .06     |
| No                       | 41 (54.7%)       | 53 (70.7%)    |         |
| Addiction                |                  |               |         |
| Yes                      | 4 (5.3%)         | 2 (2.7%)      | .681    |
| No                       | 71 (94.7%)       | 73 (97.3%)    |         |
| Greatest tumor size (mm) | 27.87 ± 16.65    | 26.37 ± 17.32 | .629    |
| T score                  |                  |               |         |

|                          |                |                |      |
|--------------------------|----------------|----------------|------|
| cT0                      | 0 (0.0%)       | 2 (2.7%)       | .564 |
| cT1                      | 19 (25.3%)     | 23 (30.7%)     |      |
| cT2                      | 46 (61.3%)     | 42 (56.0%)     |      |
| cT3                      | 6 (8.0%)       | 4 (5.3%)       |      |
| cT4                      | 4 (5.3%)       | 4 (5.3%)       |      |
| N score                  |                |                |      |
| cN0                      | 33 (44.0%)     | 46 (61.3%)     | .082 |
| cN1                      | 36 (48.0%)     | 23 (30.7%)     |      |
| cN2                      | 6 (8.0%)       | 6 (8.0%)       |      |
| Breast surgery type      |                |                |      |
| Mastectomy               | 38 (50.7%)     | 41 (54.7%)     | .744 |
| Lumpectomy               | 37 (49.3%)     | 34 (45.3%)     |      |
| Axillary surgery type    |                |                |      |
| SLNB                     | 30 (40.0%)     | 36 (48.0%)     | .411 |
| ALND                     | 45 (60.0%)     | 39 (52.0%)     |      |
| Operative duration (min) | 132.13 ± 51.13 | 135.80 ± 54.74 | .825 |
| Morphine usage           | 1.65 ± 2.39    | 2.91 ± 3.59    | .049 |

#### Participant flow diagram

- Assesed for eligibility (n=234)
  - Excluded (n=21)
  - Declined to participate (n=47)
- Randomized (n=166)
  - Pregabalin group (n=83)
    - 2 died, 2 denied to continue cooperation, 4 discontinued medication due to somnolence
    - Analyzed (n=75)
  - Placebo group (n=83)
    - 2 died, 4 denied to continue cooperation, 2 discontinued medication due to somnolence
    - Analyzed (n=75)

#### Table of variable outcomes' results

|      | Pregabalin group N = 75 | Placebo group N = 75 | P-Value     |             |        |        |
|------|-------------------------|----------------------|-------------|-------------|--------|--------|
| Time | VNRS-R                  | VNRS-A               | VNRS-R      | VNRS-A      | VNRS-R | VNRS-A |
| 24 h | 1.47 ± 1.28             | 2.15 ± 1.70          | 2.43 ± 2.04 | 3.01 ± 2.27 | .001   | .009   |
| 48 h | 0.76 ± 0.81             | 1.31 ± 0.94          | 2.20 ± 1.98 | 2.67 ± 2.08 | <.001  | <.001  |
| 1 wk | 0.71 ± 1.10             | 1.19 ± 1.24          | 1.57 ± 1.70 | 1.85 ± 1.81 | <.001  | .01    |
| 1 mo | 1.51 ± 1.35             | 1.95 ± 1.50          | 1.13 ± 1.08 | 1.69 ± 1.37 | .065   | .284   |
| 6 mo | 1.53 ± 1.36             | 2.01 ± 1.60          | 1.40 ± 1.30 | 1.84 ± 1.52 | .542   | .499   |

#### Table of adverse events

| Adverse events | Pregabalin group | Placebo group | P-Value |
|----------------|------------------|---------------|---------|
| Nausea         | 2 (2.7%)         | 19 (25.3%)    | <.001   |
| Headache       | 14 (18.7%)       | 14 (18.7%)    | 1.00    |
| Dizziness      | 20 (26.7%)       | 15 (20.0%)    | .44     |
| Blurred vision | 4 (5.3%)         | 4 (5.3%)      | 1.00    |

#### First publication date

2020-07-13, 1399/04/23

#### Abstract of published paper

**Abstract Objective:** To investigate post op pain after breast cancer surgery. **Summary background data:** Breast cancer is the most prevalent cancer among women. Current treatments made 5 year survival more than 90%. Thus there is a lot of focus on reducing morbidities due to the treatments. Post surgical pain is a common complaint, affecting 60% of patient who underwent breast cancer surgery. Through literature there are promising evidences that pregabalin can reduce post mastectomy pain. To prove this theory more data is needed. **Methods:** This is a randomized double blinded clinical trial controlled with placebo. Total number of 166 patients was randomly assigned in two groups. Pregabalin group received 75mg pregabalin 1h before surgery followed by 75mg every 12h for 15 days. Control group received placebo equivalent for the same period. We used Verbal Numerical rating scale to evaluate patients' pain at 24h, 48h, 1W, 1M and 6M after surgery. **Results:** Mean pain scores in both rest and arm abduction were significantly less in pregabalin group in 24h, 48h and 1W after surgery. There was no difference in 1 month and 6 month. Morphine usage was lower in pregabalin group. Adverse side effects such as nausea, headache, dizziness and blurred vision were not different between two groups. **Conclusions:** Perioperative use of pregabalin in breast cancer surgery is safe. It can reduce acute post op pain and morphine consumption. This study failed to show any long term effect on chronic pain.