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

City

Tehran

Province

Tehran

Postal code

1411933886

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411933886

Phone

+98 31 3668 3368

Email

Mzmasoomzadeh@yahoo.com

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411933886

Phone

+98 31 3668 3368

Email

mzmasoomzadeh@yahoo.com

Person responsible for scientific 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

Street address

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

City

Tehran

Province

Tehran

Postal code
1411933886
Phone
+98 31 3668 3368
Email
mzmasoomzadeh@yahoo.com

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
Medical doctor
Other areas of specialty/work
General Surgery
Street address
No 68, North Sindokht street, North Kargar street, Tehran
City
Tehran
Province
Tehran
Postal code
1411933886
Phone
+98 31 3668 3368
Email
mzmasoomzadeh@yahoo.com

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
    - Analized (n=75)
  - Placebo group (n=83)
    - 2 died, 4 denied to continue cooperation, 2 discontinued medication due to somnolence
    - Analized (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.