

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of the effect of stellate ganglion block and paroxetine on hot flashes and sleep disturbances in breast cancer survivors

#### Protocol summary

##### Summary

Objectives: The aim of this study is finding of new modalities in treatment of symptoms of drug induced early menopause in breast cancer survivors instead of hormone replacement therapy. Design and Participants: The study is randomized, double blind, without control of placebo, as a first trial. The sampling is made from 21 to 45 y/o breast cancer survivors, who are suffering from hot flashes and their consequences, including sleep disturbances for a minimum period of 1 month, with life expectancy greater than 6 months. Patients under treatment with chemotherapy drugs, hormones, or other known treatments of menopausal symptoms, patients with coagulation abnormalities, acute infections, cardiac diseases and ASA class  $\geq 3$  are excluded. Sample size calculated based of previous studies is 40 patients who are randomized in two groups. Intervention: In the study group stellate ganglion block was done under sonographic guidance, and in the second group, the patients received oral paroxetine for 6 weeks. Main outcomes: Times and severity of hot flashes and sleep quality in patients, were estimated before intervention, and then 2, 4 and 6 weeks after that.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016100710599N13**

Registration date: **2016-11-18, 1395/08/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-11-18, 1395/08/28

##### Registrant information

##### Name

Poupak Rahimzadeh

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6650 9059

##### Email address

p-rahimzadeh@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of medical sciences

##### Expected recruitment start date

2016-10-06, 1395/07/15

##### Expected recruitment end date

2017-02-18, 1395/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of stellate ganglion block and paroxetine on hot flashes and sleep disturbances in breast cancer survivors

##### Public title

New therapeutic methods for drug induced early menopause in breast cancer patients instead of hormone replacement therapy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: symptoms suffering for a minimum period of one month, age 21 to 45 y/o, and life expectancy greater than 6 month. Exclusion criteria:

patients under treatment with chemotherapy drugs, androgens, estrogens, progesterone analogs, or other known treatments of menopausal symptoms for example vitamin E, antidepressants and gabapentin, coagulation abnormalities, aspirin users, acute infections, cardiac diseases and ASA class  $\geq 3$ .

**Age**

From **21 years** old to **45 years** old

**Gender**

Female

**Phase**

1

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

**Street address**

Tehran - Shahid Hemmat Highway

**City**

Tehran

**Postal code****Approval date**

2016-09-18, 1395/06/28

**Ethics committee reference number**

IR.IUMS.REC.1395.28823

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

drug induced early menopause in breast cancer

**ICD-10 code**

N95 - 3

**ICD-10 code description**

Post-artificial-menopause syndrome

**Primary outcomes****1****Description**

hot flashes

**Timepoint**

before intervention and 2, 4 and 6 weeks after intervention

**Method of measurement**

Sloan and coworkers rating scale

**2****Description**

sleep quality

**Timepoint**

before intervention and 2, 4 and 6 weeks after intervention

**Method of measurement**

The Pittsburgh Sleep Quality Index (PSQI)

**Secondary outcomes**

empty

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

Advancing of oral paroxetine 7.5 mg daily for 6 weeks in control group

**Category**

Treatment - Drugs

**2****Description**

Stellate ganglion block under sonographic guidance with 10 ml of 0.5% bupivacaine in study group

**Category**

Treatment - Other

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

Hazrat-e Rasool Hospital

**Full name of responsible person**

Behzad Ebrahimi MD

**Street address**

Sattar khan - Niayesh St.

**City**

Tehran

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Vice chancellor of Research- Iran University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Musavi

**Street address**

Shahid Hemmat Expway

**City**

Tehran

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

Yes

**Title of funding source**

Vice chancellor of Research- Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Behzad Ebrahimi MD

**Position**

Anesthesiologist - Assistant fellowship of pain

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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**Full name of responsible person**

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**Position**

Anesthesiologist - Assistant fellowship of Pain

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

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behzade49@yahoo.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*