

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The effects of lidocaine infusion versus fentanyl on breast cancer cells apoptosis in patient under breast cancer surgery

#### Protocol summary

##### Study aim

Investigate the effects of lidocaine infusion versus fentanyl on breast cancer cells apoptosis in patient under breast cancer surgery

##### Design

Clinical trial with two groups of lidocaine and fentanyl, with parallel groups, double blinded , randomized based on simple randomization, with 68 patients

##### Settings and conduct

The study will be performed as a blind in the branch of the person evaluating the outcome in 68 patients with breast cancer and candidates for surgery in Imam Hossein Hospital (1300-1499). Patients enter the study after entering the operating room and obtaining full consent and explanations on how to implement the plan. After monitoring, and before the start of anesthesia, 5 cc of blood samples are taken from the patients. Induction of anesthesia is the same for everyone. Patients were randomly divided into two groups of 34: lidocaine L and fentanyl F .In group L, lidocaine infusion (120 mg / hr) and in group F, fentanyl infusion at 2 µg / kg / h. Maintenance of anesthesia during surgery is similar in both groups. 1 hour after the end of surgery, a second venous blood sample (5 cc) is taken. The samples will be numbered and then sent to a pathology laboratory for apoptosis testing. Centrifuged sera will be exposed to cultured breast cancer cells at three time intervals in 12,24,48hr and the apoptosis index in both groups will be determined and compared.

##### Participants/Inclusion and exclusion criteria

The women between 18 to 75 ASA I,II, with breast cancer undergoing mastectomy

##### Intervention groups

Lidocaine group: Lidocaine infusion during anesthesia with a dose of (120mg / hr) Fentanyl group: Fentanyl infusion during anesthesia with dose 2µg/kg/h

##### Main outcome variables

Apoptosis index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120430009593N14**

Registration date: **2021-01-19, 1399/10/30**

Registration timing: **prospective**

Last update: **2021-01-19, 1399/10/30**

Update count: **0**

##### Registration date

2021-01-19, 1399/10/30

##### Registrant information

##### Name

Elham Memary

##### Name of organization / entity

Shahid Beheshti University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7755 8082

##### Email address

drmemory@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-20, 1399/11/01

##### Expected recruitment end date

2021-12-22, 1400/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effects of lidocaine infusion versus fentanyl on breast cancer cells apoptosis in patient under breast cancer surgery

**Public title**

Evaluation of anti-tumoral effects of sera isolated from lidocaine and fentanyl infusion in the patients with breast cancer

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

female 18 to 75 years old candidate for mastectomy due to breast cancer ASA I,II

**Exclusion criteria:**

History of cardiac arrhythmias ASA IV Inflammation and infection at the surgical site History of seizures History of liver disease History of previous breast surgery except than breast biopsy Kidney failure Addiction History of mental illness

**Age**

From **18 years** old to **75 years** old

**Gender**

Female

**Phase**

1-2

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **68**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: Simple randomization  
Randomization unit: individual Randomization tool:  
Randomization will be done using the site <https://www.randomizer.org> which using random numbers extracted by the software, patients will be given one of the two groups of lidocaine (L) and Fentanyl (F).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The drugs will be prepared and coded in advance by one of the researchers present in similar 50 cc syringes. The participants who will enter the study after approving the informed consent and after explaining how to group, will enter the study, with a table of random numbers assigned to one of the infusion groups of fentanyl or lidocaine and the drug in research adjusted rapidly by the anesthesiologist in the operating room, who is not part of the research team but will be aware of the type of drug, is injected at an adjusted rate based on the patient's weight and the type of drug. Patients' blood samples will be taken from all patients before induction of anesthesia and also one hour after surgery and will be sent to a laboratory for centrifugation and apoptosis index.

Accordingly, patients and researchers (anesthesiologists and pathologists) are not aware of the type of drug and the relevant group.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

The ethical committee of Shahid Beheshti Medical University

**Street address**

Shahid Beheshti University of Medical Sciences,  
Shahid Erabi St, Ebne Yaman St, Shahid Chamran  
Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2017-09-29, 1396/07/07

**Ethics committee reference number**

IR.SBMU.MSP.REC.1396.533

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

Breast cancer

**ICD-10 code**

C50.9

**ICD-10 code description**

Malignant neoplasm of breast of unspecified site

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

Cancer Cell Apoptosis Index

**Timepoint**

Evaluation of apoptosis index in breast cancer cells after 12, 24 and 48 hours of serum exposure

**Method of measurement**

Measurement of Caspase 3, Caspase 8 and Caspase 9 factors based on immunocytochemical techniques

## Secondary outcomes

empty

## Intervention groups

1

### Description

Control group: Fentanyl infusion during anesthesia at a dose of 2 microg /kg until the end of surgery. Caspian Tamin Pharmaceutical Company

### Category

Treatment - Drugs

2

### Description

Intervention group: Infusion at a dose of 120 mg per hour until the end of surgery. Caspian Tamin Pharmaceutical Company

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam Hossein Hospital

#### Full name of responsible person

Elham Memaary

#### Street address

Imam Hossein Hospital, Shahid Madani St, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1617763141

#### Phone

+98 21 7756 7840

#### Email

drmemory@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Farzad Razaghi

#### Street address

University Blvd, Velenjak

#### City

Tehran

#### Province

Tehran

#### Postal code

1617763141

#### Phone

+98 21 2243 9781

#### Email

mpajouhesh@sbmu.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Elham Memaary

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Anesthesiology

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## Person responsible for scientific inquiries

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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**

Not applicable

**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**

Not applicable

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

Some of data can be shared.

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

Get started 6 month after printing results

**To whom data/document is available**

Surgeons and anesthesiologist and Academic Researchers

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

More research

**From where data/document is obtainable**

Elham Memory via Email

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

During an email and after its introduction, the type of expertise and explanation of the reason for requesting information, the files will be sent within 2 months

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Elham Memory

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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