

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Investigation on the effect of topical amitriptyline, ketamine and Baclofen gel for pain relief after mastectomy in patients with breast cancer

Protocol summary

Study aim

Determination of the effect of topical amitriptyline, ketamine and Baclofen gel for pain relief after mastectomy in patients with breast cancer

Design

A clinical trial with a parallel control group, double blind, randomized

Settings and conduct

After obtaining permission from the Assistant Professor of Research, 60 patients were selected in three groups of 20, one combination group and the other in the placebo group, and one group received no medication. The gel has been used locally in the pain area and should not be taken from more than 4 areas each time. Before and 4 weeks after the study, the patient's pain was recorded based on the VAS criteria, which is based on the patient's score of 0 to 10. Also, the dose of duloxetine administered to each patient after the completion of the 4-week period, if changed in the relevant checklist It turns out. All patients are also monitored for possible complications.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pain syndrome after mastectomy; At least 1 month has passed surgery; Not having other neuropathic conditions, such as shingles and diabetic neuropathy; Exclusion criteria: The presence of open sore in the surgical site; Taking painkillers

Intervention groups

Patients are randomly divided into intervention and control groups. The intervention groups, including a baclofen-amitriptyline-ketamine combination gel recipients and a placebo gel recipient group, and control group do not receive any medication.

Main outcome variables

Quality of life; irritation; anesthesia; pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N13**
Registration date: **2019-05-25, 1398/03/04**
Registration timing: **prospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-06-24, 1398/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on the effect of topical amitriptyline, ketamine and Baclofen gel for pain relief after

mastectomy in patients with breast cancer

Public title

The effect of amitriptyline, ketamine and Baclofen gel for pain relief after mastectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain syndrome after mastectomy At least 1 month has passed surgery Not having other neuropathic conditions, such as shingles and diabetic neuropathy

Exclusion criteria:

The presence of open sore in the surgical site Taking painkillers

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to one of the three groups by selecting the cards named A, B and C.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs were packaged in the same package by the pharmacist, and none of the patients and researchers knew about their contents.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713492

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

IR.SKUMS.REC.1397.092

Health conditions studied

1

Description of health condition studied

Mastectomy

ICD-10 code

Z42.1

ICD-10 code description

Encounter for breast reconstruction following mastectomy

Primary outcomes

1

Description

Quality of life

Timepoint

Before and 4 weeks after study

Method of measurement

SF 36 questionnaire

2

Description

Irritation

Timepoint

Before and 4 weeks after study

Method of measurement

Check list

3

Description

anesthesia

Timepoint

Before and 4 weeks after study

Method of measurement

Check list

4

Description

Pain

Timepoint

Before and 4 weeks after study

Method of measurement

VAS benchmark

Secondary outcomes

empty

Intervention groups

1

Description

Intervention first group: Daily, a baclofen-amitriptyline-ketamine combination gel twice a day (morning and night) at a dose of 1.3 g, is equivalent to one tbsp of topical.

Category

Treatment - Drugs

2

Description

Intervention group: Daily, a placebo gel twice a day (morning and night) at a dose of 1.3 g, is equivalent to one tbsp of topical.

Category

Placebo

3

Description

Control group: Do not get any medication.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

Rouhollah Masoumi

Street address

Shariati Blvd., Imam Ali Clinic

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Chahar-Mahal-va-Bakhtiari

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8816788640

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+98 38 3224 2696

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Rmasomi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. seyed Kamal Solati(Associate Professor of Psychology)

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Vice chancellor for research, Building No. 2,

University headquarters, Ayatollah Kashani Blvd

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nmaleeky@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Rohollah Masoumi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

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Name of organization / entity

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not 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

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Imam Ali Clinic

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

After the investigation of researcher request and presentation of required documents will be accessible.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Rohollah Masoumi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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