

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of therapeutic results and patients' satisfaction of oncoplastic techniques in surgery of breast cancer

Protocol summary

Study aim

comparison of oncoplastic breast surgery methods VS standard breast conserving surgery methods considering oncologic results and the patients satisfaction

Design

In this research, 60 eligible patients referring to Imam reza hospital of Mashad were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

All Patients in the early stage of breast cancer who referred to Imam Reza hospital(Mashhad- Iran) are included. The Informed Consent will be obtained. The randomly, patients divide into two groups to preserve the breast with the standard method or oncoplastic method. the outcomes and variables of two groups will be registered, Analyzed and compared with each other. the oncologic results will be evaluated by a surgeon and oncologist. Moreover the patients satisfaction will be assessed by a psychologist. Investigating the satisfaction and data gathering will be done by the student because the result will not be affected by facing a patient with doctor.

Participants/Inclusion and exclusion criteria

including criteria: - All the patients who are candidate for breast conserving surgery
Excluding Criteria: - chemotherapy before surgery; no postoperative radiotherapy; receiving radiotherapy during surgery; Breast cancer family history; bilateral Breast cancer; secondary breast cancer.

Intervention groups

participants will be divided randomly into 2 groups intervention group, Control group. for control group standard breast conserving surgery methods will be performed and for intervention group oncoplastic breast surgery methods will be performed

Main outcome variables

weight and volume of samples; Margin free samples based on millimeter; Patient satisfaction measurement

questionnaire based on Harris scale for Cosmetic Results System.

General information

Reason for update

Acronym

BCS

IRCT registration information

IRCT registration number: **IRCT20111207008316N4**

Registration date: **2018-02-06, 1396/11/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-06, 1396/11/17**

Update count: **0**

Registration date

2018-02-06, 1396/11/17

Registrant information

Name

Mehdi Asadi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1852 5255

Email address

asadimh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-10-18, 1396/07/26

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic results and patients' satisfaction of oncoplastic techniques in surgery of breast cancer

Public title
Evaluation of outcomes of oncoplastic techniques in surgery of breast cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All the Patients who are candidate for Breast conserving surgery
Exclusion criteria:
Chemotherapy before surgery no postoperative radiotherapy receiving radiotherapy during surgery
Breast cancer family history Bilateral Breast cancer
Secondary Breast cancer

Age
No age limit

Gender
Female

Phase
1-2

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random table method

Blinding (investigator's opinion)
Single blinded

Blinding description
All of the patients who are candidate for breast conserving surgery will be included in this study and divided (Random table method) in 2 groups. Based on BMI and Age matching will be performed for this 2 groups (Group matching Method)

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Mashhad University of Medical sciences

Secondary trial Id
95157

Registration date
1396-05-17, 777/01/-671

Ethics committees

1

Ethics committee

Name of ethics committee

mashad university of medical sciences

Street address

mashad, university st, next to cinema hoveyzeh,
mashad university of medical sciences, the Vice
Chancellor for Research of Mashhad University of
Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2017-10-18, 1396/07/26

Ethics committee reference number

...IR.MUMS.fm.REC.1396.19721.04.96

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

Z85.3

ICD-10 code description

Malignant neoplasm

Primary outcomes

1

Description

free margin based on millimeter

Timepoint

Just after performing surgery based on pathologic report

Method of measurement

Based on pathologic studies on the tumor samples and
free margin (millimeter) and evaluation of hormon
receptors and biologic markers for tumors

Secondary outcomes

1

Description

Patient satisfaction measurement questionnaire

Timepoint

first week after surgery, First month after surgery, 6
Month after surgery

Method of measurement

Satisfaction with Harris scoring system is collected from

all patients as follows in the first week, the first month and the sixth month after surgery.

Intervention groups

1

Description

Intervention group: performing oncoplastic surgery methods for intervention group participants

Category

Treatment - Surgery

2

Description

Control group: performing standard breast conserving surgery methods

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital of Mashhad

Full name of responsible person

Mehdi Asadi

Street address

Mashhad , Emam reza hospital Square, Emam reza hospital

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9137913316

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+98 51 3180 2557

Email

asadimh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

ghorshi building, Daneshgah Avenue

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asadimh@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of medical Sciences

Full name of responsible person

Mehdi Asadi

Position

Associated Professor of surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mehdi Asadi

Position

Associate professor of surgery

Latest degree

Specialist

Other areas of specialty/work

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Fax**Email**

asadimh@mums.ac.ir

Web page address**Fax****Email**

asadimh@mums.ac.ir

Web page address**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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data obtained is confidential and can be provided with the code

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

All educational and research centers of medical universities

Under which criteria data/document could be used

Any analysis on the data will be possible with the permission of the Main author

From where data/document is obtainable

Main author

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

Sending an email and request from the main implementer of the project

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

Mashhad University of Medical Sciences

Full name of responsible person

Mehdi Asadi

Position

Associate Professor of Surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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