Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessing the effect of Diclofenac suppository on post-operative pain of Mastectomy

Protocol summary

Study aim
Assessing the relevance between age and the effectiveness of Diclofenac Suppository, Assessing the relevance between addiction and the effectiveness of Diclofenac Suppository, Assessing the relevance between surgery time and the effectiveness of Diclofenac Suppositoy

Design
Clinical trial, without control group, phase 2, on 44 patients that candidated for Mastectomy that was referred to the Khatam-al-Anbia Hospital in Shahrood in 98-99.

Settings and conduct
After the surgery, thr duration of surgery recorded in the questionnaire and Diclofenac suppository is given to the patient and pain intensity is measured at zero and 10 oclock at night

Participants/Inclusion and exclusion criteria
Informed consent Age 18 years old and more The patient it candidate for Mastectomy

Intervention groups
The patients are candidate for Mastectomy

Main outcome variables
Assessing the effectiveness of Diclofenac Suppository on post-operative pain of mastectomy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210505051191N1**
Registration date: **2021-06-01, 1400/03/11**
Registration timing: **retrospective**

Last update: **2021-06-01, 1400/03/11**
Update count: **0**

Registration date
2021-06-01, 1400/03/11

Registrant information

Name
Naghmeh Soroosh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3222 1761

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
2019-12-22, 1398/10/01

Actual recruitment end date
2021-03-20, 1399/12/30

Trial completion date
2021-03-20, 1399/12/30

Scientific title
Assessing the effect of Diclofenac suppository on post-operative pain of Mastectomy

Public title
Assessing the effect of Diclofenac suppository on post-operative pain of Mastectomy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent Age 18 years old and more The patient it candidate for Mastectomy

Exclusion criteria:

The patients disappointment

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Shahrood

Street address

Khatam-al-Anbia Hospital, Daneshgah Blvd

City

Shahrood

Province

Semnan

Postal code

3614871151

Approval date

2020-12-27, 1399/10/07

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1399.044

Health conditions studied

1

Description of health condition studied

The effectiveness of Diclofenac suppository

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of pain after Mastectomy

Timepoint

Immediately after surgery and 10 oclock at night

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Diclofenac suppository, 100 mg, after the surgery

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-al-Anbia Hospital

Full name of responsible person

Naghmeh Soroosh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

mohammad hossein hasani

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Seyedeh Fatemeh Amirkhalili
Position
Assisstant professor
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to

make this available