

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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 Suppository

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

Email address

naghiii.sss.1994@gmail.com

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

Street address
Khatam-al-Anbia Hospital, Daneshgah Blvd

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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
Assistant professor
Latest degree
Specialist
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Person responsible for updating data

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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