

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of Agitation in recovery after mastectomy in patients receiving dexamethasone in comparison with placebo in Imam Khomeini Hospital Operating room, 1391-1392

Protocol summary

Summary

The objective of this double-blinded randomized control trial was to evaluate the efficacy of dexamethasone versus placebo in preventing post-operative agitation in 116 patients who underwent mastectomy. The inclusion criterion was being 18-65 years old. In this study, patients were randomized to two groups; the first group (dexamethasone group) was treated with 8 milligrams of intravenous dexamethasone and the second group (placebo group) was assigned to 2 milliliters of sterile water after induction of anesthesia and before intubation. During recovery patients were evaluated for incidence and severity of agitation, severity of pain, occurrence of nausea and vomiting and degree of somnolence after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306139213N2**

Registration date: **2014-01-08, 1392/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-08, 1392/10/18

Registrant information

Name

Jalil Makarem

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1576

Email address

j-makarem@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Because the drugs were routinely used for anesthesia, the patient is responsible for project cost ,it includes his medical expenses

Expected recruitment start date

2012-09-19, 1391/06/29

Expected recruitment end date

2013-12-31, 1392/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Agitation in recovery after mastectomy in patients receiving dexamethasone in comparison with placebo in Imam Khomeini Hospital Operating room, 1391-1392

Public title

Comparison of Agitation in recovery after mastectomy in patients receiving dexamethasone in comparison with placebo in Imam Khomeini Hospital Operating room, 1391-1392

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. aged between 18 and 65 years 2. mastectomy surgery Exclusion criteria: 1. antiemetic consumption after surgery 2. a positive history of psychiatric or CNS disorders 3. having diabetics or

uncontrolled blood pressure 4. analgesic consumption before surgery 5. a history of substance abuse consuming or other medications

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Ethics Committee

Street address

Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd , Tehran

City

Tehran

Postal code

Approval date

2013-08-04, 1392/05/13

Ethics committee reference number

899/130/92/5

Health conditions studied

1

Description of health condition studied

agitation

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

agitation

Timepoint

10 minutes after transfer to recovery room

Method of measurement

By applying the standard RASS questionnaire (attached) post-anesthesia agitation is assessed 10 minutes after transfer to recovery room. This questionnaire consists of 10 levels (from +4 to -5) in which values more than +1 are considered emergent delirium or agitation per se.

Secondary outcomes

empty

Intervention groups

1

Description

Group 1 placebo: 2 milliliters sterile water, IV during 30 seconds

Category

Prevention

2

Description

Group 2, dexamethasone group: 8 milligrams dexamethasone, IV, post-induction and pre-intubation, during 30 seconds

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Jalil Makarem

Street address

Tehran University of Medical Sciences, Poursina st, 16th Azar st, Enghelab eslami square, Tehran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr.Jalil Makarem

Position
Assistant Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty