

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Compare the effect of supplemental fluid therapy before and during breast cancer surgery on severity of post-operative nausea and vomiting and severity of pain.

Protocol summary

Summary

Post operative nausea and vomiting (PONV) and pain are the most common complications after breast cancer surgery. The aim of this study is the compare of supplemental fluid therapy before and during breast cancer surgery on severity of post-operative nausea and vomiting and severity of post-operative pain. In this study, 60 patients who need to breast cancer surgery with age of 18-50 years old, without renal and cardiac disorder and weight below 100 kg, randomly assign in three groups. In the first group, all of patients receive usual fluid therapy in preoperative and during surgery. In the second group, all of the patients receive 5 cc/kg ringer-lactate serum at least 2 hours before surgery beside the usual fluid therapy. In the third group, all of the patients receive 5 cc/kg ringer-lactate serum during surgery beside the usual fluid therapy. Then, the severity of PONV and postoperative pain will be evaluated by a person who is not aware from groups of study. Severity of PONV and post-operative pain compare in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602116481N8**
Registration date: **2016-03-01, 1394/12/11**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-01, 1394/12/11

Registrant information

Name

Mohsen Soleimani

Name of organization / entity

Semnan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of supplemental fluid therapy before and during breast cancer surgery on severity of post-operative nausea and vomiting and severity of pain.

Public title

Compare the supplemental fluid therapy before and during breast cancer surgery on post-operative nausea and vomiting and pain after cancer breast surgery.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-50 years; ASA (American Society of Anesthesiologists) physical status

classification I and II. Exclusion criteria: History of smoking; renal or cardiac disorder; unusual bleeding during surgery; weight above 100 kg; uncontrolled hypertension.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, 5th kilometer of Damghan road, Semnan, Iran.

City

Semnan

Postal code

Approval date

2016-02-09, 1394/11/20

Ethics committee reference number

IR.SEMUMS.REC.1394.169

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Post-operative nausea and vomiting

Timepoint

1, 4, 8, 24 hours after breast cancer surgery

Method of measurement

Post-operative nausea and vomiting questionnaire (Cortila)

Secondary outcomes

1

Description

Severity of pain

Timepoint

1, 4, 8, and 24 hours after surgery

Method of measurement

Visual analog scale

Intervention groups

1

Description

Intervention group 1: In this group, all of the patients beside the routine fluid therapy before and during breast cancer surgery, receive 5 cc/kg ringer-lactate serum from fasting time until 2 hours before surgery.

Category

Prevention

2

Description

Control group: In this group all of patients receive routine fluid therapy before and during breast cancer surgery.

Category

Other

3

Description

Intervention group 2: In this group, all of the patients beside the routine fluid therapy before and during breast cancer surgery, receive 5 cc/kg ringer-lactate serum during surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohaday-Tajrish hospital

Full name of responsible person

Mohsen Soleimani

Street address

Semnan University of Medical Sciences

City

Semnan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Ali Rashidy-pour

Street address

Semnan University of Medical Sciences

City

Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Semnan 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**

Semnan University of Medical Sciences

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PhD in nursing

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Web page address**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*