Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Duloxetine administeration on postoperative pain after abdominal hysterectomy compared to the placebo

Protocol summary

Study aim

Effect of preoperative duloxetine administration on decreasing VAS score of women undergoing total abdominal hysterectomy post operatively compared to control group at Moheb Yas hospital in Tehran

Design

This study will be a double-blind randomized clinical trial and patient will randomly divided into control and duloxetine receiving groups,The sample size was 50 individuals based on analysis of variance of repeated measures, with 25 individuals in each group.

Settings and conduct

It's a double blind randomized clinical trial (patient and anesthesiologist Will be unaware of the type of medication received)it will performed at Moheb Yas Hospital in Tehran,women's candidates for abdominal hysterectomy with inclusion criteria will divide randomly into two groups of duloxetine recipients 2 hours before surgery and the control group who will receive placebo.they undergo general anesthesia, and at the end of the operation, patients with a VAS score greater than 4 receive 2 mg morphine sulfate and then will record PONV and the first time they need the drug and the total amount of the drug received within the first 24 hours after surgery

Participants/Inclusion and exclusion criteria

All 30-60 year old women with ASA class 1-2 who underwent elective abdominal hysterectomy at Tehran Moheb Yas Hospital within the study time and are willing to participate in this study Those who are allergic to the drug, or have a surgery longer than 3 hours, have a diagnosis of cancer after surgery or discover any other pelvic pathology in operation, need additional surgery, or any technique than pfannenstiel incision will excluded from the study

Intervention groups

Case who will receiving duloxetine 60 mg 2 hours before surgery and control group who will receiving placebo two hours before surgery

Main outcome variables

In need of analgesia,pain intensity, type of drug used, nausea, vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120624010102N2**
Registration date: **2019-12-10, 1398/09/19**
Registration timing: **prospective**

Last update: **2019-12-10, 1398/09/19**
Update count: **0**

Registration date

2019-12-10, 1398/09/19

Registrant information

Name

Ehsan Bastan hagh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-08-18, 1399/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Duloxetine administeration on postoperative pain after abdominal hysterectomy compared to the placebo

Public title

effect of duloxetine on post operative pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female age 35-65 Elective total abdominal hysterectomy ASA class 1 & 2

Exclusion criteria:

patient refusal Any alergic history with Duloxetine or other SNRIs surgery longer than 3 hours Postoperative cancer diagnosis or any other pelvic pathology during the operation Need additional surgery Any other incision than Pfannenstiel

Age

From **35 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly allocated to 2 groups using balanced block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

The study medications are prepared by an anesthesiologist who does not otherwise participated in the study and then enveloped and sealed and patient's code are recorded on it.The enveloped will open 2 hours before induction by an anesthesiologist who is blinded to patient's study group and type of solution.All of the nurses and patient's are blinded to the type of solution and to the patient's study group allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

5th flour, Corner of ghods St, Keshavarz Blv.

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Province

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Postal code

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Approval date

2018-07-23, 1397/05/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.286

Health conditions studied

1

Description of health condition studied

control of acute post operative pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

30 min ,1 , 2 , 6 ,12 hours after surgery

Method of measurement

VAS score

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

0 to 12 hours postoperative

Method of measurement

Asking

Intervention groups

1

Description

Intervention group: Oral duloxetine capsule 60 mg (Kharazmi Pharmacy) 2 hours before surgery(SNRI)

Category

Treatment - Drugs

2

Description
Control group: Placebo 2 hours before surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
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Sponsors / Funding sources

1

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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
Tehran 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
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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