Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessment of duloxetine effect on post-operative pain and recovery in patients who undergo abdominal hysterectomy under general anesthesia

Protocol summary

Study aim

the main objective of this study is evaluating the effect of duloxetine on post-operative pain in abdominal hysterectomy.

Design

This is a randomised double blind clinical trial (phase 2-3) with blinded postoperative care and outcome assessment. The number of subjects is 70. The subjects are divided in 2 groups randomly using table of random numbers.

Settings and conduct

This study is performed on patients with hysterectomy surgery in Afzalipoor Hospital of Kerman. The person who perform the intervention is a nurse out of this study which gives the patients drug or placebo, so anesthesiologist, the patient and data collector and analyzer are unaware of used drug.

Participants/Inclusion and exclusion criteria

This study is a clinical trial on patients who are admitted in Afzalipoor Hospital of Kerman for hysterectomy which are given consent to participation. Exclusion criteria are long term usage of opioids a analgesics, taking steroids, age less than 18 and higher than 85, pregnancy, history of heart, hepatic and renal failure, uncontrolled hypertension, endocrine disorders, BMI more than 40.

Intervention groups

Patients in case group receive oral duloxedine 60 mg, 2 hours prior to surgery and patients in control group receive placebo. Anesthesia technique and medication in both groups are identical.

Main outcome variables

In all cases, vital signs, complications of duloxetine and amount of analgesics given to patient are checked prior to anesthesia; just after commence of surgery; at the time of giving isoflurane; during surgery and after operation and recovery time, every 15 minutes. The intensity of pain after anesthesia until discharge from recovery is determined and recorded. evaluation of pain in recovery is performed by means of Visual Analogue Scale (VAS). Patients discharged from recovery If they have scores of 9 or 10 according to aldrete scoring system. The amount of given analgesics in 24 hours is measured and overall patient satisfaction is assessed according to postoperative quality of recovery (QOR) score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120922010900N5**
Registration date: **2018-02-13, 1396/11/24**
Registration timing: **prospective**

Last update: **2018-02-13, 1396/11/24**
Update count: **0**

Registration date

2018-02-13, 1396/11/24

Registrant information

Name

Hosein Sattari

Name of organization / entity

kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of duloxetine effect on post-operative pain and recovery in patients who undergo abdominal hysterectomy under general anesthesia

Public title

Assessment of duloxetine effect on post-operative pain and recovery in patients who undergo abdominal hysterectomy under general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients admitted to Afzalipoor Hospital for hysterectomy surgery ASA classification of I (without systemic disease) and II (with controlled systemic disease) informed consent of patient for participation

Exclusion criteria:

long term usage of opioids steroid thrapy age less than 18 and more than 85 year pregnancy heart, hepatic and renal failure uncontrolled hypertension endocrine diseases BMI greater than 40 heart rate less than 50 evidence of heart block in ECG presence of suizure, epilepsy and bipolar disorders surgery lasting more than 3 hours huge bleeding during surgery

Age

From **18 years** old to **85 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

the simple randomization is used to dividing the patients in 2 groups by means of table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

two hours before surgery, oral capsule of duloxetine is given to patients in case group and placebo (similar capsule containing starch) in control group. so, anesthesiologist, the patient and data collector are unaware of the kind of used drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical sciences

Street address

Jomhoori boulevard

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Postal code

7619813159

Approval date

2017-12-18, 1396/09/27

Ethics committee reference number

IR.KMU.REC.1396.1917

Health conditions studied

1

Description of health condition studied

postoperative pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

postoperative pain

Timepoint

The level of pain is measured and documented every 15 minutes after patient reorientation, until discharge from recovery room.

Method of measurement

Visual Analogue Scale (VAS) is used for pain assessment

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

24 hours after surgery

Method of measurement
postoperative quality of recovery (QOR) score

2

Description
vital signs
Timepoint
every 15 minutes
Method of measurement
authomathic monitoring system

Intervention groups

1

Description
Intervention group: two hours prior to surgery, patients in this group receive 60 mg oral capsule of duloxetine; brand name of Loxeta, made by Abidi pharmaceutical company.
Category
Treatment - Drugs

2

Description
Control group: in this group, patients receive placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipoor Hospital
Full name of responsible person
Hossein Sattari
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Sponsors / Funding sources

1

Sponsor
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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
Kerman 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)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
postoperative pain patient satisfaction of recovery
When the data will become available and for how long
data will be available just after publication in journal.
To whom data/document is available
data will be available for people working in academic institutions.
Under which criteria data/document could be used
they can repeat statistical analysis.
From where data/document is obtainable
contact via email address of responsible person
What processes are involved for a request to access data/document
after confirming identity of requested person.
Comments